Supreme Court, U.S.
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IN THE

Supreme Court of the United States

October Term, 1995

HOWMEDICA INC.,

Petitioner,

v.

MARILYN HAUDRICH, as Executor and Sole Legatee of Donald Haudrich, Deceased,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of the State of Illinois

PETITION FOR WRIT OF CERTIORARI

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE & FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record

Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350
Counsel for Petitioner

QUESTION PRESENTED

Whether a state court may properly rely on its procedural waiver rule to assert subject matter jurisdiction over tort claims involving a medical device despite the fact that Congress has explicitly granted the Food and Drug Administration ("FDA") exclusive jurisdiction over matters concerning the safety and effectiveness of medical devices, including the power to police compliance with its exclusive federal regulatory scheme, and has expressly preempted state law requirements relating to the safety and effectiveness of such devices.

RULE 29.6 STATEMENT

Petitioner's parent company is Pfizer Inc. Petitioner has no non-wholly owned subsidiary companies.

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21 C.F.R. §§ 807.81, 860.84, 888.3560 (1995);

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No. ___

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1995

HOWMEDICA INC.,

Petitioner,

v.

MARILYN HAUDRICH, as Executor and Sole Legatee of Donald Haudrich, Deceased,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of the State of Illinois

PETITION FOR WRIT OF CERTIORARI

Petitioner Howmedica Inc. ("Howmedica") hereby petitions for a writ of certiorari to review the judgment of the Illinois Supreme Court in this case. The Illinois Supreme Court held that preemption under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-395 (1994), is non-jurisdictional in nature, but rather is in the nature of an affirmative defense, and was waived by a defendant who did not raise it until after trial, even though the FDCA grants the Food and Drug Administration ("FDA") exclusive authority to regulate and review the safety and effectiveness of medical devices, and to police compliance with its exclusive federal regulatory scheme.

OPINIONS BELOW

The opinion of the Illinois Supreme Court in *Haudrich v. Howmedica, Inc.* is reported at 169 Ill. 2d 525, 662 N.E.2d 1248 (1996) (App. 2a-20a). The opinion of the Illinois Appellate Court is reported at 267 Ill. App. 3d 630, 642 N.E.2d 206 (1995) (App. 21a-47a). The judgment of the Illinois Circuit Court for the 20th Judicial Circuit, St. Clair County, is not reported (App. 48a). The order of the Illinois Supreme Court denying appellant's petition for rehearing is not reported (App. 49a).

JURISDICTION

The Illinois Supreme Court entered judgment on January 18, 1996. Howmedica filed a timely petition for rehearing on February 8, 1996, which the Illinois Supreme Court denied on April 1, 1996 (App. 49a). This Court has jurisdiction under 28 U.S.C. § 1257(a) (1988).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Appendix E (App. 50a-66a) sets forth verbatim the following statutory and regulatory provisions: 21 U.S.C. §§ 360(k), 360c(f)(1), (i), 360e(a), (c), 360j(g), 360k(a), (b) (1994); 21 C.F.R. §§ 807.81, 860.84, 888.3560 (1995); 53 Fed. Reg. 51,007 (Dec. 12, 1988).

STATEMENT OF THE CASE

Medtronic v. Lohr, Nos. 95-754 and 95-886, which was recently argued in this Court, presents this Court with the question whether state-law tort claims involving the design, manufacture, and labeling of medical devices are preempted by the FDCA. Should this Court hold that any of such claims is in fact preempted by federal law, this case presents a further question concerning the nature and scope of such preemption with regard to the subject matter jurisdiction of state courts over such claims generally.

The Illinois Supreme Court held that preemption under the FDCA was non-jurisdictional in nature, and thus waivable by a defendant. That holding conflicts in principle with previous decisions of this Court, and with the legislative intent behind the FDCA, specifically the Medical Device Amendments of 1976. This Petition asks the Court to review this matter, in light of its anticipated holding in *Medtronic v. Lohr*, Nos. 95-754 and 95-886, and to determine whether FDCA preemption is jurisdictional in nature and thus deprives state courts of the ability to review the safety and efficacy of medical devices generally.

A. Background and Significance of the Federal Law Question

In 1976, Congress passed the Medical Device Amendments to the FDCA (the "MDA"), 21 U.S.C. § 360 *et seq.* (1994). The MDA established a comprehensive federal scheme that placed regulation of the development, approval, and distribution of medical devices within the exclusive domain of the FDA. Pursuant to that authority, the FDA has promulgated extensive *regulations* setting forth in great detail the federal regulatory process to be followed by all manufacturers seeking approval to market and sell medical devices within the United States. See 21 C.F.R. § 800.10 *et seq.* (1995). By enacting the MDA, Congress explicitly intended to establish a regulatory framework that balanced the public's health and safety with respect to medical devices, on the one hand, with the need to encourage innovation in medical technology and to protect against disparate state-law requirements that might stifle such innovation, on the other. H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976).

Congress struck this balance by granting the FDA exclusive authority over the development, review, approval, and policing of the manufacture and marketing of medical devices. The exclusivity of the FDA's regulatory and administrative authority is assured by the express preemption provision in the MDA, which reads in part:

> Except as provided in subsection (b), . . . no State or political subdivision of any state may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1994) (App. 58a). Congress specifically intended for this provision to be interpreted as a "general prohibition on non-Federal regulation."[1/] See H.R. Rep. No. 853, *supra*, at 45. In this way, Congress determined that the FDA would be given sole responsibility to consider and decide issues regarding the safety and effectiveness of medical devices, thereby helping to ensure the public's health and safety. S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070-71.

The FDA has exercised its exclusive authority by promulgating an extensive regulatory framework governing medical devices generally, in conformity with the three-part classification scheme established by the MDA. The extent of the FDA's regulations for each classification category reflects the FDA's determination of the level of oversight necessary or appropriate to ensure the safety and efficacy of the

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1/ Congress also gave the FDA exclusive authority to determine whether to grant a State a discretionary exemption from this sweeping preemption to permit more stringent regulation of a medical device, or a different state-law requirement based on compelling local conditions. See 21 U.S.C. § 360k(b) (1994) (App. 58a). The State of Illinois has not applied for or been granted any such authority with respect to the device at issue in this action.

particular type of device. See 21 U.S.C. § 360c(b) (1994). See also 21 C.F.R. § 860.84 (1995) (App. 60a-63a). Each manufacturer of a medical device must give the FDA advance notice of its intent to market the device and state the class in which the device is classified. See 21 U.S.C. § 360(k) (App. 50a).

Class I devices include those which the FDA has determined pose no unreasonable health risks; accordingly, they are subject only to the general regulatory controls established by the FDA for all devices. See 21 U.S.C. § 360c(a)(1)(A) (1994). Class II devices include those which the FDA has determined may require additional special controls, such as performance standards and postmarket surveillance, to assure safety and effectiveness. *Id.* § 360c(a)(1)(B). The final category, Class III devices, includes devices represented to be life-sustaining or life-supporting, or which the FDA has determined to present a potentially unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C). All devices on the market prior to the enactment of the MDA are automatically deemed to be Class III devices until reclassified by the FDA. *Id.* § 360c(f)(1) (App. 50a-51a).

The MDA also establishes three distinct means by which the FDA can review a medical device and approve it for use in the United States. First, the FDA regulates clinical experimentation with new devices through its Investigational Device Exemption ("IDE") regulatory process. Under this procedure, the FDA reviews detailed information submitted by the manufacturer concerning the device and a proposed experimental plan, and determines whether the device may be distributed solely for use in approved research studies. See 21 U.S.C. § 360j(g) (1994) (App. 54a-58a); 21 C.F.R. Pt. 812 (1995).

Second, the FDA reviews some Class III devices pursuant to the "premarket approval" ("PMA") process prior to marketing. Under the PMA process, the manufacturer must submit sufficient information, including clinical data, to demonstrate the safety and effectiveness of the device before the FDA will approve its marketing. See 21 U.S.C. § 360e(a), (c) (1994) (App. 52a-54a); 21 C.F.R. Pt. 814 (1995).

Finally, for Class III devices developed after the MDA was enacted that are not subject to the PMA requirements, the MDA establishes a premarket review and clearance method known as the

"510(k) process." Under the 510(k) process, the FDA reviews information submitted by a manufacturer to determine whether the device is "substantially equivalent" to an existing device or a device introduced prior to the MDA's enactment (collectively, "predicate devices") that the agency has allowed to be marketed without an approved PMA. See 21 U.S.C. § 360c(f)(1), (i) (1994) (App. 50a-52a); 21 C.F.R. § 807.81 (1995) (App. 59a-60a). In the event that the FDA subsequently determines that a device originally cleared under the 501(k) process should be reviewed under the PMA process, it can promulgate a regulation requiring PMAs. See 21 U.S.C. § 360e(b) (1994).

The medical device at issue in this case is an artificial knee device known as the P.C.A.® Total Knee System that is used for total knee replacement. When first introduced in 1981, the FDA classified the device as a Class II device as labelled for use only with bone cement, and cleared it through the 510(k) process, finding that it was substantially equivalent to predicate devices already on the market prior to enactment of the MDA. See 21 C.F.R. § 888.3560 (1995) (App. 63a); 53 Fed. Reg. 51,007 (Dec. 12, 1988) (App. 64a-66a). Howmedica later sought FDA authorization to conduct a clinical study and investigation of the use of the P.C.A.® Total Knee System without bone cement, with the FDA eventually granting approval of the IDE and authorizing a clinical investigation in 1981. When the clinical investigation was completed, Howmedica submitted a PMA for the device to be labelled for use without bone cement in 1985. 53 Fed. Reg. 51,007 (Dec. 12, 1988) (App. 64a-66a). The FDA granted premarket approval of the PMA in 1988. *Id.* As a result of this premarket approval, the P.C.A.® Total Knee System is now classified as a Class III device.

B. Facts and Circuit Court Proceedings

The original plaintiff in this case, Donald Haudrich, filed a complaint in the Illinois Circuit Court for the 20th Judicial Circuit (St. Clair County) on April 18, 1989.[2/] The complaint alleged claims based

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2/ Mr. Haudrich died from causes unrelated to the device at issue during the pendency of this case before the Illinois Appellate Court.

on negligence, breach of warranty, design defect, defective manufacture, and failure to warn regarding a P.C.A.® Total Knee System manufactured by Pfizer Hospital Products Group, Inc., d/b/a Howmedica, Inc. Plaintiff alleged that he had a total joint replacement operation at age 45 in November 1985, after injuring his knee in a fall at work in 1983. The surgeon allegedly told plaintiff that the P.C.A.® Total Knee System would last approximately ten years, give or take two years, and would then need to be replaced. The replacement knee device failed earlier than anticipated approximately three years later and was revised successfully by further surgery in 1989. Following a bench trial, the Court awarded damages related to the failure of the device and the revision surgery of $1,686,988.70.

C. The Illinois Appellate Court Opinion

Howmedica appealed the Circuit Court's judgment to the Illinois Appellate Court for the Fifth District, raising the issue of federal preemption of Mr. Haudrich's claims in its opening brief on appeal. Howmedica pointed out that the MDA's preemption was jurisdictional in nature, and therefore had not been, and could not be, waived. The Appellate Court addressed the issue of preemption on the merits but held that the MDA did not bar entry of a damages award against Howmedica based on negligent failure to warn and defective design or manufacture of the Class III medical device (App. 21a-37a). In reaching this decision, the Court ruled that for purposes of 21 U.S.C. § 360k(a), a judgment issued by a state trial court cannot constitute a "requirement" that is "different from, or in addition to" those of the FDA. The Court affirmed the judgment below after rejecting all other challenges raised by Howmedica (App. 47a).[3/]

D. The Illinois Supreme Court Opinion

Howmedica filed a petition for leave to appeal to the Illinois Supreme Court, seeking review of the Appellate Court's rulings on preemption and other issues. The Illinois Supreme Court granted leave on February 1, 1995. Howmedica addressed the issue of preemption extensively. In particular, Howmedica asserted that the issue of

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3/ The Appellate Court published only the portion of its decision that pertained to the issue of federal preemption.

preemption went to the trial court's subject matter jurisdiction, with the MDA depriving the state court of jurisdiction to render a judgment for damages based on a state-law tort claim that the medical device was defective or unreasonably dangerous. The Illinois Supreme Court noted that the Appellate Court had addressed the merits of Howmedica's preemption argument. Nonetheless, it decided to address the question whether Howmedica had waived the preemption issue by failing to raise it in the trial court. The Court concluded that the Illinois procedural rule on waiver applied. Thus, because preemption was not specifically pursued in the trial court, the Court held it could not be raised for the first time on appeal (App. 8a-11a).

In reaching this holding, the Illinois Supreme Court rejected Howmedica's reliance on this Court's reasoning in *International Longshoremen's Ass'n v. Davis*, 476 U.S. 380 (1986), which held that state courts lack power to adjudicate state-law claims that are preempted by the NLRA. The Illinois Supreme Court distinguished *Davis* on the ground that the FDA's exclusive domain over medical devices did not represent a choice by Congress to vest that agency with sole authority to address issues involving the safety and effectiveness of medical devices, as compared to the NLRB's jurisdiction in *Davis*:

> [U]nlike in *Davis*, Congress has not designated another forum for the resolution of disputes concerning medical devices. Although Congress has enacted a body of substantive law dealing with such devices, it has not " 'confide[d] primary interpretation and application of its rules to a specific and specially constituted tribunal.' " Thus, the issue here does not involve a choice of forum but instead concerns whether State tort or Federal statutory law controls. Under these circumstances, the issue of preemption is not jurisdictional but is in the nature of an affirmative defense
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> . . . .

(App. 10a-11a) (citations omitted). In reaching its decision, the Illinois Supreme Court also relied on the recent (and similarly flawed) decision of the First Circuit in *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8 (1st Cir. 1995), *cert. denied*, 116 S. Ct. 1568 (1996).

REASONS FOR GRANTING THE WRIT

I. THIS CASE PRESENTS AN IMPORTANT FEDERAL QUESTION WHICH SHOULD BE SETTLED BY THIS COURT, PARTICULARLY IN LIGHT OF THIS COURT'S GRANT OF CERTIORARI IN *MEDTRONIC, INC. V. LOHR.*

The scope of federal preemption of medical device claims is an issue of national importance that grows weightier over time, as innovation in technology and advances in medicine lead to vast increases in the use of medical devices of every sort. This Court recognized the importance of this issue when granting certiorari in *Medtronic, Inc. v. Lohr*, Nos. 95-754 and 95-886, which was recently argued. Because this Court is presently considering the scope of the MDA's preemptive effect on state-law tort claims concerning medical devices in that case, this petition will not reiterate the arguments already presented to the Court in favor of broad federal preemption.

This case presents a *second* issue of national importance dependent on the outcome of that case. Should this Court hold that state-law tort claims involving medical devices are in fact preempted by federal law, this case presents a further question regarding the nature and scope of that preemption and of the subject matter jurisdiction of state courts over such claims generally. Specifically, this case presents the question whether state courts may overlook or ignore the scope of federal preemption by relying on state procedural rules that reflect concerns related to the administration of cases between individual litigants, rather than looking to the national legislative and regulatory policies over substantive areas, such as the medical device industry as a whole, which are served by federal preemption.

To be sure, state courts generally should be free to enact reasonable procedural requirements for asserting and proving up affirmative defenses in the ordinary course of their judicial functions. Such powers over procedure, however, cannot be utilized as a means of *expanding* a state court's jurisdiction when Congress has determined to expressly confer that jurisdiction exclusively on a federal regulatory authority such as the FDA. When subject matter jurisdiction based on a claim of federal preemption is questioned--regardless of which stage

in the court's proceedings–a state court *must* address that question. See *Davis*, 476 U.S. at 388.

To hold otherwise, and instead to leave the determination whether to bring the issue of federal preemption before a state court solely in the hands of the parties, would undermine the comprehensive congressional scheme reflected in the MDA as well as the authority of the FDA to promulgate and enforce medical device regulations and requirements of universal application. This Court has held consistently that the States are not free to rely on procedural rules that "impose unnecessary burdens" on the assertion of other federally created rights, e.g., *Brown v. Western Railway*, 338 U.S. 294, 296 (1949) (state pleading rule is inapplicable to claim under Federal Employers' Liability Act because a "federal right cannot be defeated by the forms of local practice"), or to "have the final say as to what defenses [may] be properly interposed" when determining the incidents of federal rights generally. E.g., *Dice v. Akron, Canton & Youngstown R.R. Co.*, 342 U.S. 359, 361 (1952) (validity of release under the Federal Employers' Liability Act is governed by federal law). States are no more free to rely on procedural hurdles that have the effect of permitting state regulation in the field of medical devices that is plainly proscribed by Congress.

A party's failure to comply with state court procedural rules cannot be the test for whether a court has subject matter jurisdiction in an area otherwise completely preempted by federal law. Surely the FDA cannot be made to track every lawsuit involving a medical device to preserve its exclusive regulatory role in this field. Application of a waiver rule as applied by the Illinois Supreme Court in this case should not be permitted to undermine national policy concerning significant matters affecting the public health.

For these reasons alone, this Court should grant certiorari in this case, given the importance of the issue presented, and reverse the holding of the Illinois Supreme Court.[4/] At a minimum, this Court

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4/ This case presents a more compelling basis for certiorari than *Violette v. Smith & Nephew Dyonics, Inc.*, *supra*, in which the First Circuit relied on a federal procedural waiver rule to reject a claim that the MDA preempted plaintiff's state-law tort claims involving a medical device. Here, a state court invoked its state-law procedural rule to defeat the applicability of a federal preemption

should defer action on this petition pending its decision in *Medtronic, Inc. v. Lohr*, and if necessary, vacate and remand this case for consideration in light of the Court's announced decision in that case.

II. THE ILLINOIS SUPREME COURT DECISION CONFLICTS, IN PRINCIPLE, WITH SUPREME COURT DECISIONS.

The Illinois Supreme Court decision here conflicts, in principle, with this Court's decision in *International Longshoremen's Ass'n v. Davis*, *supra*. The Illinois Supreme Court failed to find *Davis* controlling despite the substantial similarities between congressional intent for preemption under the MDA and the National Labor Relations Act (the "NLRA"). Ten years after it was decided, the underlying jurisdictional preemption analysis of *Davis* remains fundamentally sound. This Court should confirm its holding in that case and reverse the decision below, and thereby protect against improper incursions by courts of general jurisdiction into the exclusive regulatory domain of the FDA over medical devices. Otherwise, important considerations of national policy will, as a practical matter, be left in the hands of private litigants, an outcome that Congress never intended.

In *Davis*, a defendant union raised a claim of preemption based on the NLRA *after* having lost a trial on the merits, asserting that plaintiff was required to bring his claims before the NLRB, rather than in a court of law. This Court held that the state courts lack the power to adjudicate claims based on state law to the extent that the state law was preempted by the NLRA, and, as a consequence, the defendant could assert preemption at any time, even after trial on the merits. *Davis*, 476 U.S. at 398-99.

The Illinois Supreme Court misconstrued the framework for preemption analysis established by *Davis*, by viewing the issue as one that concerned "whether State tort or Federal statutory law controls," rather than involving a "choice of forum." By so holding, the Court failed to recognize the comprehensive and exclusive powers of the FDA

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command, thereby permitting state regulation in an area explicitly proscribed by Congress, with the interests of the Federal Government not being at least minimally represented by either the FDA or the federal judiciary.

to regulate and police medical devices, similar to the powers of the NLRB to regulate and police the field of collective bargaining.

The critical question is whether Congress established a regulatory scheme with preemptive scope such that it reflects "a nonwaivable foreclosure of the state court's very jurisdiction to adjudicate." *Davis*, 476 U.S. at 389. *Davis* establishes a clear and distinct framework for determining whether a state court has jurisdiction in the face of express federal preemption:

> [T]he point is not whether state law gives the state courts jurisdiction over particular controversies but whether jurisdiction provided by state law is itself pre-empted by federal law vesting exclusive jurisdiction over that controversy in another body. It is clearly within Congress' powers to establish an exclusive federal forum to adjudicate issues of federal law in a particular area that Congress has the authority to regulate under the Constitution. Whether it has done so in a specific case is the question that must be answered when a party claims that a state court's jurisdiction is pre-empted. Such a determination of congressional intent and of the boundaries and character of a pre-empting congressional enactment is one of federal law.

476 U.S. at 387-88 (citations omitted).

The starting point, therefore, is whether federal law vests exclusive jurisdiction over the subject matter of a particular area of concern in a federal regulatory or administrative authority. It is beyond dispute that Congress granted the FDA exclusive authority to regulate the development, marketing, and use of medical devices, e.g., *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir. 1994) ("Congress enacted the MDA to give the [FDA] comprehensive control over medical devices"), in order to protect medical devices against disparate state requirements "in addition to" or "differing from" the requirements established by the FDA pursuant to the regulatory scheme created by the MDA. Consequently, federal law has vested exclusive jurisdiction over the subject matter of medical device *regulation* in the FDA.

Likewise, Congress granted the FDA the exclusive *power to police* the development, marketing, and use of medical devices--including

adherence to FDA's regulations--by various means, including civil and criminal actions. E.g., *Reeves v. AcroMed Corp.*, 44 F.3d 300, 307 (5th Cir.) (the FDCA was designed to "establish an extensive enforcement scheme under which the FDA bears primary responsibility for policing violations of its regulations"), *cert. denied*, 115 S. Ct. 2251 (1995). In particular, the FDA has broad authority to withdraw approval of a device should it determine that the device is unsafe or its labeling inadequate, 21 U.S.C. § 360e(e) (1994); to order a recall of the device, *id.* § 360h(e); to impose civil penalties for violations of the MDA or FDA regulations, *id.* § 333(g)(1)(A); and to initiate criminal prosecutions, through the Department of Justice, against manufacturers who fail to comply with the MDA or adhere to FDA regulatory standards. *Id.* § 333(a). In addition, the FDA can order a manufacturer to repair, replace, or offer a refund for a device that it determines presents an unreasonable risk of substantial harm to the public health. *Id.* § 360h(b). Likewise, a court may, as part of any sentence in a criminal judgment against a medical device manufacturer, award restitution to those harmed.[5/] See 18 U.S.C. § 3663(a)(1) (1994).

As the First Circuit recently explained, the reasoning behind Congress's delegation of authority to the FDA is clear:

> To avoid the possibility of disuniform treatment, Congress placed enforcement authority in the FDA. . . . Centrally situated and with the requisite expertise, the FDA is in the best position to determine whether the provisions of the MDA have in fact been violated and to ensure that the law is applied in a uniform manner. Given the FDA's central enforcement role, the preemptive scope of § 360k(a) becomes clear . . . .

Talbott v. C.R. Bard, Inc., 63 F.3d 25, 29-30 (1st Cir. 1995) (citations omitted), *cert. denied*, __ S. Ct. __, 64 U.S.L.W. 3593 (June 3, 1996).

5/ Howmedica acknowledges that under this statute, restitution in criminal cases may not include compensation for pain and suffering or punitive damages. See 18 U.S.C. § 3663(b)(2) (1994).

The FDA's exclusive police powers, which ensure compliance with its regulations and protection of the public health, are buttressed by the fact that Congress granted no private right of action in favor of a medical device recipient or user to enforce the MDA and the FDA's regulations promulgated thereunder. E.g., *Talbott*, 63 F.3d at 30. Rather, the sole remedy in the event of a failure of a manufacturer to abide by federal device requirements is to seek FDA scrutiny and remedial action.

This is not a "choice of law" issue. There is no substantive law from which a state court may "choose" when faced with a tort claim involving a medical device. The MDA is not merely a substantive rule of law to be enforced or applied by any competent tribunal with general subject matter jurisdiction for state-law tort claims. Rather, Congress has *eliminated* all prospect of state regulation of medical devices by any means, absent an express exemption granted by the FDA pursuant to its exclusive discretionary authority.[6/] The MDA and its accompanying FDA regulations provide for exclusive FDA oversight of medical devices, and reflect, like the NLRA, a "complex and interrelated federal scheme of law, remedy, and administration," *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 243 (1959), for which this Court should hold that "due regard for the federal enactment requires that state jurisdiction must yield." *Id.* at 244.

In *Garmon*, this Court recognized the dangers of permitting courts to assert jurisdiction over matters of national significance that Congress intended (impliedly, in the case of the NLRA) to be assigned solely to a federal administrative authority, emphasizing that:

6/ The discretionary exemptions permitted in § 360k(b) are similar to the power of the National Labor Relations Board under the NLRA to agree to cede jurisdiction over labor disputes to a particular state agency, see 29 U.S.C. § 160(a) (1994), or to decline jurisdiction over a particular class or category of employers, *id.* § 164(c). Based on the similarities of these exemption powers, the fact that the FDA has power to grant an exemption provides no basis for distinguishing the scope of jurisdictional preemption provided by the two statutes.

> the States as well as the federal courts must defer to the exclusive competence of the National Labor Relations Board if the danger of state interference with national policy is to be averted.

359 U.S. at 245.

The issue in this case, as in *Garmon*, is simply one of proper deference to the federal regulatory authority empowered to take all necessary measures with regard to the development, marketing, and use of medical devices, i.e., the FDA. One of the few key differences between the NLRB and the FDA, of course, is that in the case of the MDA, Congress did *more* than merely leave this Court with an *inference* that it intended to divest state and federal courts of jurisdiction over the relevant subject matter. See *Davis*, 476 U.S. at 393, n.11 (noting that "the exclusive nature of [the NLRB's] jurisdiction was not explicitly noted by Congress"). To avoid all uncertainty with respect to medical device regulation, Congress instead *explicitly* stated (in § 360k(a)) that the States may not "establish or continue in effect . . . any requirement . . . which is different from, or in addition to, any [federal] requirement . . . which relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a) (1994) (App. 58a). By this language, coupled with the structure and purpose of the MDA and the FDA's regulatory scheme generally, Congress intended to deprive state courts of the power to review the safety and effectiveness of medical devices by vesting exclusive authority in the FDA. See *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (Congress's intent may be "explicitly stated in the statute's language or implicitly contained in its structure and purpose").

As *Davis* also made clear,

> That the entity chosen to administer those laws is administrative rather than judicial . . . does not alter the pre-emptive effect of the federal law. Consequently, *a procedural default in state court does not protect a state-court judgment from pre-emption.*

476 U.S. at 393, n.11 (emphasis added). Congress undoubtedly chose to rely on the wisdom and experience of the FDA in an area requiring particular scientific and medical expertise, often involving new frontier

technologies well beyond the general competency of state legislators, judges and jurors. The fact that the "forum" chosen by Congress is administrative in nature, and not judicial, with a statutory framework that fails to provide for private causes of action against device manufacturers, is no oversight. To the contrary, it reflects a reasoned judgment well within the realm of Congress's legislative authority under the Interstate Commerce Clause. As one district court recently observed,

> This judgment represents a permissible decision by Congress that the public interest will best be served by relying exclusively on the FDA to strike the proper balance between reasonably assuring safety and promoting innovation with regard to new devices that have the potential both to enhance and injure human health.

Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 40 (D. Mass. 1994), *aff'd*, 63 F.3d 25, *supra*. Moreover, innovation and safety are not mutually exclusive. In fact, innovation often leads to enhanced safety.

In short, the explicit preemption language of § 360k(a), coupled with the broad and exclusive powers of the FDA to promulgate regulations governing the development, marketing, and use of medical devices and to police such activities nationwide, reflects an explicit choice by Congress to *extinguish* subject matter jurisdiction of courts of general jurisdiction with respect to *all* matters concerning the safety and effectiveness of such devices.

Whether plaintiff has a remedy before the FDA or in federal court comparable to the remedy otherwise provided by state law is not the focus of the inquiry. Rather, the question is whether the state court lacked subject matter jurisdiction over plaintiff's medical-device related claims. As this Court in an analogous situation explained in *Avco Corp. v. Aero Lodge No. 735*, 390 U.S. 557, 561 (1968):

> The nature of the relief available after jurisdiction attaches is, of course, different from the question whether there is jurisdiction to adjudicate the controversy. . . . [T]he breadth or narrowness of the relief which may be granted under federal law . . . is a distinct question from whether the court has jurisdiction over the parties and the subject matter.

(holding that whether a claim "arises" under federal law for purposes of removal jurisdiction is not determined by the scope of any federal remedy that might be available).[7/]

As in *Davis*, the preemption claim presented by the MDA is one that "go[es] to the State's actual adjudicatory or regulatory power." 476 U.S. at 391, n.9. It is clear that Congress intended to oust state courts as fora to adjudicate and, by means of damages claims, establish diverging standards for evaluating the safety and effectiveness of medical devices. Like the NLRA, Congress specifically intended to "confide primary interpretation and application of [the MDA's] rules to a specific and specially constituted tribunal," *id.* at 389 (quoting *Garner v. Teamsters*, 346 U.S. 485, 490 (1953)), in this case the FDA.

The decision below failed to recognize the importance of carefully considering the analytical framework established in *Davis*. Instead, the Illinois Supreme Court fundamentally erred in its analysis by simply declaring, in conclusory fashion, that the issue presented by the MDA did not involve a "choice of forum" question but instead simply concerned whether state tort law or federal statutory law applied (App. 10a). This conclusory approach is inconsistent with the dictates of *Davis*, and fails to give proper deference to Congress's grants to the FDA of exclusive jurisdiction over both the promulgation of regulations and requirements applicable to medical devices, and remedial actions relating to the safety and effectiveness of such devices. This failure to follow *Davis* in an area of important national policy requires this Court's considered review.

7/ For this reason, this Court has explicitly rejected the notion that a state-law cause of action can be "completely preempted" (for purposes of federal removal jurisdiction) only if the federal law not only preempts the state claim, but also provides a superseding federal remedy to replace it. See *Caterpillar Inc. v. Williams*, 482 U.S. 386, 391, n.4 (1987).

CONCLUSION

For all of the foregoing reasons, this Court should grant certiorari in this case and reverse the holding of the Illinois Supreme Court. At a minimum, this Court should defer action on this petition pending its decision in *Medtronic, Inc. v. Lohr*, and if necessary, vacate and remand this case for consideration in light of the Court's announced decision in that case.

Respectfully submitted,

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE &
FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record
Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350

Counsel for Petitioner

Dated: June 14, 1996

APPENDIX

APPENDIX A - (*Haudrich v. Howmedica Inc.*, 169 Ill. 2d 525, 662 N.E.2d 1248 (1996)) 2a

APPENDIX B - (*Haudrich v. Howmedica Inc.*, 267 Ill. App. 3d 630, 642 N.E.2d 206 (Ill. Ct. App. 1995)) (Opinion) . . . 21a

APPENDIX C - (*Haudrich v. Howmedica Inc.*, No. 89-L-357 (Ill. Cir. Ct., for the 20th Judicial Circuit (St. Clair County), December 2, 1992)) (Judgment) 48a

APPENDIX D - (*Haudrich v. Howmedica Inc.*, No. 78319 (Ill. Sup. Ct. April 1, 1996)) (Order denying petition for rehearing) 49a

APPENDIX E - (setting forth verbatim the following statutory and regulatory provisions:

21 U.S.C. §§ 360(k), 360c(f)(1), (i), 360e(a), (c), 360j(g), 360k(a), (b) (1994);

21 C.F.R. §§ 807.81, 860.84, 888.3560 (1995);

53 Fed. Reg. 51,007 (Dec. 12, 1988)) 50a

APPENDIX A - OPINION OF THE ILLINOIS SUPREME COURT DATED JANUARY 18, 1996

MARILYN HAUDRICH, Ex'r and Sole Legatee of Donald Haudrich, Deceased, Appellee,

v.

HOWMEDICA, INC., *et al.*, Appellants.

Docket No. 78319

James V. O'Brien, Thomas L. Caradonna, Lewis, Rice & Fingersh, L.C., St. Louis, MO, for Howmedica Inc.

Thomas Q. Keefe, Jr., P.C., and Harriet Homsher Hamilton, of Cook, Shevlin, Ysursa, Brauer & Bartholomew, Ltd., Belleville, for appellee.

Stephanie A. Scharf and Deirdre A. Fox of Kirkland & Ellis, Chicago, for amici curiae Health Industry Manufacturers Association, Abbott Laboratories, and Baxter International Inc.

Donnella Rice, Washington, D.C., for amicus curiae Health Industry Manufacturers Association.

Mark E. Barmak and Eric S. Palles, Abbott Park, for amicus curiae Abbott Laboratories.

F. Samuel Eberts III, Deerfield, for amicus curiae Baxter International Inc.

CHIEF JUSTICE BILANDIC delivered the opinion of the court:

The plaintiff, Donald Haudrich, brought this action for strict products liability in the circuit court of St. Clair County against defendant Howmedica, Inc., and for negligence against codefendant, Michael Lukens, a Howmedica sales representative. The plaintiff

sought damages for injuries allegedly caused by a defective prosthetic device that had been surgically inserted into his knee. The plaintiff alleged that Howmedica designed, manufactured and sold the device that, at the time it left Howmedica's possession and control, was defective and unreasonably dangerous. He further alleged that Lukens negligently and carelessly sold the defective device and negligently and carelessly failed to warn of the device's defective and unreasonably dangerous condition. Following a bench trial, the trial court entered a judgment against the defendants and awarded the plaintiff damages of $1,686,989.70. The appellate court affirmed. (267 Ill. App. 3d 630.) We allowed the defendants' petition for leave to appeal. 145 Ill. 2d R. 315[1/]

The primary issue presented in this appeal is whether provisions of the United States Food, Drug, and Cosmetic Act of 1938 (Act) (21 U.S.C. §301 *et seq.* (1970)) preempt the plaintiff's State-law tort claims. Specifically, the defendants point to the Medical Device Amendments of 1976 (21 U.S.C. §§351 through 360 (1994)) as barring the plaintiff's claims. The appellate court rejected this contention, holding instead that the United States Congress did not intend to preempt common law tort actions by passing the Medical Device Amendments. The appellate court declined to address the plaintiff's argument that the defendants waived the issue of preemption by failing to raise it in the trial court.

The defendants also contend that the evidence was insufficient to prove that the plaintiff was injured by an unreasonably dangerous condition of the knee device, that the award of damages was excessive, and that the appellate court erred in finding that they waived the issue of whether Lukens' negligence had been sufficiently proved.

1/ The plaintiff died during the pendency of this appeal, and his wife, Marilyn, was substituted as the plaintiff in this action. For simplicity's sake, all references to "the plaintiff" herein should be understood to mean the decedent.

FACTS

In 1993, the plaintiff sustained a work-related injury to his left knee and subsequently underwent a series of treatments to improve his condition. When these treatments failed, the plaintiff opted for a total knee replacement. The plaintiff's treating physician, Dr. William Simmons, selected the "PCA Total Knee System" manufactured by Howmedica. This device received premarket approval by the Federal Food and Drug Administration in September 1988, three years after the plaintiff's surgery.

The surgery was performed in November 1985. The plaintiff was allowed to return to work one year later. Approximately 2½ years after the surgery, the plaintiff complained to Dr. Simmons of "popping" inside his knee joint. In May 1988, the plaintiff began complaining of pain, swelling and instability in his knee. A few months later, the plaintiff felt something snap inside the back of his knee and shortly thereafter, the decision was made to replace the prosthetic knee device. At the time the initial surgery was performed, Dr. Simmons had informed the plaintiff that the knee prosthesis would last approximately 10 years, give or take two years, and that it would eventually need to be replaced. Charles Lawyer, Howmedica's director of quality assurance, testified that he was unable to say how long the knee device should last, since its longevity depended on numerous factors. The prosthetic device implanted in the plaintiff's knee failed in less than three years.

The PCA Total Knee System is comprised of three components. The component at issue is comprised in part of a piece of polyethylene plastic which rests inside a metal tray and is situated on top of the shin bone. While performing the "revision" surgery in January 1989, Dr. Simmons discovered that the polyethylene piece attached to the first knee implant had "almost completely worn away," and he found "multiple shavings of this particular plastic" behind the plaintiff's knee joint. Dr. Simmons determined that the plastic piece had slipped from its original position, which explained the plaintiff's statement that something in the knee had "popped." At a deposition, Dr. Simmons testified that when he implanted the first device, he did not expect the plastic failure to occur. He had used the device in the past and had 3

been satisfied with its performance. Based on his findings during the second surgery, Dr. Simmons opined that the first knee prosthesis failed to perform as reasonably intended, based on a reasonable degree of medical and scientific certainty. He could not identify anything in his surgical technique or in the plaintiff's physical makeup that could explain the device's failure. Although the plaintiff had a deformity in his legs which caused bowleggedness, this condition did not contribute to the premature wear of the polyethylene piece. Dr. Simmons found no evidence that the plaintiff had abused the prosthesis.

The second knee replacement differed from the first in that the thickness of the polyethylene piece was nine millimeters as opposed to seven. Bone cement was also used to hold the second device in place whereas a cementless process was used to secure the first one. Dr. Simmons explained that the nine-millimeter model was available at the time of the initial surgery, but he opted for the thinner model because it required less of the plaintiff's bone to be removed, and Howmedica representatives advised that the thinner model be used to preserve bone mass. At that time, Howmedica had not yet recommended that doctors discontinue using the seven-millimeter model. Sometime after the initial surgery, Howmedica began advising doctors to use the thicker model because the other model was "perhaps a little too thin." Dr. Simmons criticized the seven-millimeter polyethylene as being too thin.

After the second surgery, the plaintiff was unable to return to work, and it was not anticipated that he would ever be able to do so. According to Dr. Simmons, the plaintiff continued to complain of pain in his knee even after the second surgery. At the time of trial in July 1992, the plaintiff complained of pain, stiffness, swelling and some instability of the knee. Dr. Simmons stated, however, that the plaintiff was "much better off" having had the second surgery.

Dr. Simmons explained, however, that with every successive knee replacement, the knee becomes more and more unstable. He stated that after a certain number of revisions, it becomes necessary to insert a prosthesis which locks together. After a third or fourth revision, the insertion of that type of prosthesis may have become necessary for the plaintiff. However, it would not have become necessary if the plaintiff

had needed only two surgeries in his lifetime, as Dr. Simmons had contemplated, given the plaintiff's age and the anticipated lifespan of the device. Dr. Simmons also noted that subsequent revision surgeries increase the risk of infections, nerve damage, and vessel injury and make rehabilitation more difficult. He added that the expected life of a revision implant tends to decrease as the number of revisions increases. At the time of trial in 1992, the cost of a revision surgery, according to Dr. Simmons, was between $25,000 and $30,000.

The plaintiff's expert witness, Roy D. Bloebaum, Ph.D., testified as to his expertise in the analysis of prosthetic devices. In the course of his research, he investigated a problem with respect to the premature wear of polyethylene in various prosthetic devices and co-authored numerous articles on the subject. Dr. Bloebaum testified that the minimum life expectancy of the PCA Total Knee System was 10 to 12 years, with 18 to 20 years not being unreasonable. Dr. Bloebaum cited one study which reported that 65% of knee devices which predated the PCA device survived 17 years. Dr. Bloebaum agreed that the survivability of a device depended on many factors, including the manner of use and the patient's weight. He saw nothing in the plaintiff's physical makeup that would have adversely affected the lifespan of the knee device. He did not criticize Howmedica's use of the polyethylene material since that was all that was available at the time the device was manufactured, but he did criticize the fact that the polyethylene was processed using heat, which made it susceptible to certain defects like pitting, scratching and "delamination," whereby the polyethylene breaks apart in layers. The specific design errors he noted in addition to the heat processing were concentrated stresses on the femoral component of the device which fits over the polyethylene and the use of a polyethylene plastic piece that had an inadequate thickness. According to Dr. Bloebaum, these design characteristics lead to premature wear and failure of the device. He opined to a reasonable degree of scientific certainty that these characteristics caused the product to be unreasonably dangerous and defective. He eliminated misalignment in the plaintiff's case as a cause of the device's failure.

Defendants' expert, Dr. John Lyons, a specialist in total joint reconstruction, testified that the prosthesis was implanted at an excessive angle, which was the cause of the premature wear of the

polyethylene plastic. He based this opinion on a review of post-operative X rays and on an analysis of the knee device that was removed from the plaintiff's body. In Dr. Lyons' opinion, neither the thickness of the polyethylene insert nor the heat processing played any role in the failure of the plastic.

Stephen Hirsch, Howmedica's director of sales and formerly its director of marketing for reconstructive products, testified concerning a Howmedica publication entitled the "Polyethylene Awearness Series." The publication was undertaken because orthopedic surgeons were becoming "quite concerned" about premature wear of the polyethylene piece used in the knee device and about the increasing number of revision surgeries having to be performed. A Howmedica bulletin acknowledged that questions were being asked by orthopedic surgeons about implant design, insert thickness, contact stresses and material composition as they related to polyethylene wear. Through the "Awearness Series," Howmedica sought to determine if premature wear could result from a design which subjected the polyethylene plastic to contact stresses, from an insert that was too thin, or from the heat processing method Howmedica used. Hirsch concluded they were all factors but added that there were other factors which could also explain the premature wear of the polyethylene piece. Howmedica ultimately determined, at some point after the plaintiff's first surgery, that a seven-millimeter plastic piece was too thin and eventually advised doctors to stop using it. Hirsch agreed that if premature failure resulted from contact stresses, the use of heat to process the piece, and inadequate polyethylene thickness, the product would be considered unsafe.

Howmedica's vice president of product development, Peter Van Syckle, testified for the defendants that the design of the PCA Total Knee System was not defective. He acknowledged that the particular device implanted in the plaintiff's knee could have been defective and agreed that the polyethylene plastic failed. However, he stated that other factors besides those claimed by the plaintiff could have caused the failure. Van Syckle defined a defective product as one that does not perform in a "reasonably anticipated way" and acknowledged the testimony of Dr. Simmons, as the user of the device, that the product did not perform as reasonably anticipated.

ANALYSIS

A. Preemption

The defendants contend that section 360k of the Medical Device Amendments to the Act (21 U.S.C. §360k (1994)) expressly preempts the plaintiff's State law tort claims. As previously stated, the appellate court rejected this contention, concluding instead that Congress did not intend to preempt common law tort actions by enacting the Medical Device Amendments. The appellate court declined to address the plaintiff's claim that the defendants waived the issue of preemption by failing to raise it in the trial court. We, however, have decided to address the issue. For the reasons which follow, we hold that the waiver doctrine should apply to the situation presented here.

It is well settled that issues not raised in the trial court are deemed waived and may not be raised for the first time on appeal. (See *Daniels v. Anderson* (1994), 162 Ill. 2d 47, 58-59; *Geise v. Phoenix Co. of Chicago, Inc.* (1994), 159 Ill. 2d 507, 514-15; *Lannom v. Kosco* (1994), 158 Ill. 2d 535, 539-40; *Mittelman v. Witous* (1989), 135 Ill. 2d 220, 230.) In *Daniels*, this court reiterated that "'the theory upon which a case is tried in the lower court cannot be changed on review, and *** an issue not presented to or considered by the trial court cannot be raised for the first time on review.'" (*Daniels*, 162 Ill. 2d at 58, quoting *Kravis v. Smith Marine, Inc.* (1975), 60 Ill. 2d 141, 147.) We concluded that allowing the defendant to change his theory of defense on appeal would "not only weaken the adversarial process and our system of appellate jurisdiction" (*Daniels*, 162 Ill. 2d at 59), but would likely prejudice the plaintiff, since he may have been able to present evidence to discredit the theory had it been raised in the evidence presentation stage, that is to say, in the trial court. *Daniels*, 162 Ill. 2d at 59.

Similarly, in *Geise*, this court concluded that the theory the defendant attempted to raise for the first time on appeal, which was based on a State statutory provision, was in the nature of an affirmative defense and, as such, was waived by not being presented initially in the trial court. (*Geise*, 159 Ill. 2d at 514.) In finding waiver, the court in *Geise* determined that the situation presented was not one in which "some basic legal impediment exist[ed] to a claim or defense on which the judgment [was] based," nor was it "a situation where a party

need[ed] to be rescued from some inadvertent blunder it or its attorney made at trial," (*Geise*, 159 Ill. 2d at 514.) This court determined, rather, that the defendant had made a purely strategic decision not to raise the statute-based theory at trial in the hope that the plaintiff's common law negligence claim would fail and it would escape liability entirely. The court emphasized that "our responsibilities as a court of review do not extend to protecting a party from its own failed trial strategy." *Geise*, 159 Ill. 2d at 514-15.

The defendants in this case argue, however, that the claim of preemption is not in the nature of an affirmative defense but is a jurisdictional matter which cannot be waived and which may be raised at any time. Specifically, they argue that section 360k of the Medical Device Amendments deprives State courts of jurisdiction to render judgments for damages based on State tort law for defective or unreasonably dangerous medical devices which have received premarket approval by the Food and Drug Administration. We reject this argument. Initially, we note that on at least one occasion, this court has recognized that a party's failure to invoke the Federal preemption doctrine in the trial court may preclude him from raising it on appeal. (See *Beckman v. Freeman United Coal Mining Co.* (1988), 123 Ill. 2d 281, 286.) Moreover, we find the Supreme Court's decision in *International Longshoremen's Ass'n v. Davis* (1986), 476 U.S. 380, 90 L. Ed. 2d 389, 106 S. Ct. 1904, upon which the defendants primarily rely in support of their claim that the issue of Federal preemption is jurisdictional, to be inapposite to the case at bar.

Davis involved the application of the National Labor Relations Act (NLRA). There, the Supreme Court held that the appellant's preemption claim was not a waivable affirmative defense because the claim went to the trial court's power to adjudicate the case. In so ruling, the Court found that Congress had deprived courts of jurisdiction to decide cases involving conduct that is or may likely be protected by the NLRA, and it did so by "vesting exclusive jurisdiction over [the] controversy in another body," namely, the National Labor Relations Board. (*Davis*, 476 U.S. at 388, 90 L. Ed. 2d at 398, 106 S. Ct. at 1910). The Court noted:

> "'Congress did not merely lay down a substantive rule of law to be enforced by any tribunal competent to apply law generally to the parties. It went on to confide primary interpretation and application of its rules to *a specific and specially constituted tribunal* and prescribed a particular procedure for investigation, complaint and notice, and hearing and decision, including judicial relief pending a final administrative order.'" (Emphasis added.) (*Davis*, 476 U.S. at 399, 90 L. Ed. 2d at 399, 106 S. Ct. at 1911, quoting *Garner v. Teamsters, Chauffeurs & Helpers Local Union No. 776* (1953), 346 U.S. 485, 490, 98 L. Ed. 228, 239, 74 S. Ct. 161, 165-66.)

The Court emphasized that it was "essential" to the administration of the NLRA that determinations with respect to activities within the purview of that statute "'be left in the first instance to the National Labor Relations Board.'" *Davis*, 476 U.S. at 390, 90 L. Ed. 2d at 400, 106 S. Ct. at 1911, quoting *San Diego Bldg. Trades Council v. Garmon* (1959), 359 U.S. 236, 244-45, 3 L. Ed. 2d 775, 783, 79 S. Ct. 773, 779.

In short, the *Davis* Court determined that the issue on review was not whether the State court erroneously decided a matter of Federal law in a case within its jurisdiction or whether Federal or State law governed a case properly before the State's courts. Rather, the situation involved a State court "'finally and erroneously asserting its jurisdiction to deal with a controversy which [was] beyond its power and instead [was] within the exclusive domain of the National Labor Relations Board.'" (*Davis*, 476 U.S. at 390-91, 90 L. Ed. 2d at 400, 106 S. Ct. at 1912, quoting *Local No. 438 v. Curry* (1963), 371 U.S. 542, 548, 9 L. Ed. 2d 514, 519 83 S. Ct. 531, 536.) In other words, the Court noted, the issue was a choice-of- forum rather than a choice-of-law question. *Davis*, 476 U.S. at 391, 90 L. Ed. 2d at 401, 106 S. Ct. at 1912.

In the present case, however, unlike in *Davis*, Congress has not designated another forum for the resolution of disputes concerning medical devices. Although Congress has enacted a body of substantive law dealing with such devices, it has not "'confide[d] primary

interpretation and application of its rules to a specific and specially constituted tribunal.'" (*Davis*, 476 U.S. at 389, 90 L. Ed. 2d at 399, 106 S. Ct. at 1911, quoting *Garner v. Teamsters* (1953), 346 U.S. 485, 490, 98 L. Ed. 228, 239, 74 S. Ct. 161, 165-66.) Thus, the issue here does not involve a choice of forum but instead concerns whether State tort or Federal statutory law controls. Under these circumstances the issue of preemption is not jurisdictional but is in the nature of an affirmative defense, subject to the traditional rules of appellate adjudication, including timely presentment of issues and waiver.

Under circumstances virtually identical to those presented here, the First Circuit Court of Appeals, in *Violette v. Smith & Nephew Dyonics, Inc.* (1st Cir. 1995), 62 F.3d 8, applied the waiver rule where the defendant failed to argue at trial the issue of preemption over State products liability claims pursuant to the Medical Device Amendments. The court held that the defendant would not be permitted to "'evade the scrutiny of the [trial] court *** on appeal with a new claim in order to create essentially a new trial.'" (*Violette*, 62 F.3d at 11, quoting *G.D. v. Westmoreland School District* (1st Cir. 1991), 930 F.2d 942, 950.) We concur in this view. Moreover, we have found several appellate court decisions of this State and numerous Federal court decisions to be in accord with this approach as well. (*See, e.g., Zook v. Norfolk & Western Ry. Co.* (1994), 268 Ill. App. 3d 157, 164; *Yates v. Doctor's Associates, Inc.* (1990), 193 Ill. App. 3d 431, 438. *See also Piekarski v. Home Owners Savings, F.S.B.* (8th Cir. 1992), 956 F.2d 1484, 1489; *Sweeney v. Westvaco Co.* (1st Cir. 1991), 926 F.2d 29, 36-41; *Dueringer v. General American Life Insurance Co.* (5th Cir. 1988), 842 F.2d 127, 130: *Johnson v. Armored Transport of California, Inc.* (9th Cir. 1987), 813 F.2d 1041, 1043-44; *Gilchrist v. Jim Slemons Imports, Inc.* (9th Cir. 1986), 803 F.2d 1488, 1496-97.) Neither the plaintiff nor the trial judge in this case had his "rightful opportunity to address the question in the first instance" (*Violette*, 62 F.3d at 11), and for this reason we hold that the issue of preemption is waived. We thus save for another day the question of whether the Medical Device Amendments to the Act, and specifically section 360k, preempt the sort of State-law tort claim raised by the plaintiff here.

We turn now to the remaining issues the defendants raise on appeal.

B. Sufficiency of the Evidence

The defendants first contend that there was insufficient evidence to support a finding that the plaintiff was injured by an unreasonably dangerous condition of the knee device.

It is axiomatic that a manufacturer has a duty to use reasonable care in the design and manufacture of its product, bearing in mind the intended and actual uses of the product. (*Buehler v. Whalen* (1977), 70 Ill. 2d 51, 60-61.) In order for a plaintiff to recover in strict liability, his injury must be shown to result from a condition of the product, the condition must be unreasonably dangerous, and the condition must have existed at the time the product left the manufacturer's control. (*Hunt v. Blasius* (1978), 74 Ill. 2d 203, 210.) In an attempt to once again define the term "unreasonably dangerous condition," the court in *Hunt* agreed that "'those products are defective which are dangerous because they fail to perform in the manner reasonably to be expected in light of their nature and intended function.'" (*Hunt*, 74 Ill. 2d at 211, quoting *Dunham v. Vaughan & Bushnell Manufacturing Co.* (1969), 42 Ill. 2d 339, 342.) The court went on to find that a condition or defect in a product is unreasonably dangerous if it subjects those exposed to the product to an unreasonable risk of harm beyond that which would be contemplated by the ordinary person with ordinary knowledge common to the community as to the product's characteristics. *Hunt*, 74 Ill. 2d at 212, citing Restatement (Second) of Torts §402A, Comment i (1965). See also *West v. Deere & Co.* (1991), 145 Ill. 2d 177, 180.

Applying the foregoing principles to the present case, we hold that sufficient evidence was presented at trial to find Howmedica strictly liable for the plaintiff's injuries.

Dr. Simmons testified that, based on information he received from Howmedica representatives at seminars and based on his background and experience, he believed the plaintiff's knee replacement would last 10 years, give or take two years. The plaintiff's expert witness, Dr. Bloebaum, testified at trial that the minimum life expectancy of the Howmedica device was 10 to 12 years, and that it was not unreasonable to expect it to last 18 to 20 years. Although both doctors agreed that numerous factors dictated the survivability of the device, neither found that the plaintiff's physical makeup, his physical activities or the

placement of the device in the plaintiff's body was a factor leading to the premature failure of the polyethylene insert after less than three years. Both doctors opined that the device failed to live up to its intended function, based on a reasonable degree of medical and scientific certainty, primarily because of the inadequate thickness of the polyethylene insert, which Howmedica itself later recognized.

Dr. Bloebaum's examination of the device at issue revealed delamination, or separation of the polyethylene, as well as pitting and scratching, which he testified were consistent with a design that uses a heat-pressing technique. While he had no quarrel with Howmedica's use of the polyethylene material, he testified that the defects apparent in the device were magnified by the combination of heat pressing, the inadequacy of the plastic's thickness, and contact stresses. Dr. Bloebaum opined that the device was defective and unreasonably dangerous on these bases.

Although Howmedica's vice president of product development, Van Syckle, testified that the design of the knee device was not defective, he acknowledged that the polyethylene insert failed and agreed that the device implanted in the plaintiff's knee could have been defective. He also agreed that the company's manufacturing technique using heat may have contributed to accelerated wear of the polyethylene but disagreed that the thickness of the plastic was a factor. Howmedica's expert, Dr. Lyons, opined that Dr. Simmons' misalignment of the device in the plaintiff's body and the plaintiff's activities after surgery were the causes of the device's failure. Dr. Lyons agreed that all of the radiologist's reports indicated that the device was in excellent alignment, but he nevertheless concluded that Dr. Simmons' failure to comply with appropriate medical standards led to its premature failure.

Despite the testimony of Howmedica's experts to the contrary, sufficient evidence was presented to support a finding that the device failed to perform in a manner reasonably expected in light of its nature and intended function and subjected the plaintiff to an unreasonable risk of harm beyond that contemplated by an ordinary person. We conclude that the plaintiff met his burden of proving that his injuries resulted

from an unreasonably dangerous condition of the Howmedica knee device.

C. Damages

The defendants also contend that the damages award totaling $1,686,988.70 was excessive.

The rule that findings of a trial court sitting without a jury will not be disturbed unless manifestly erroneous is equally applicable to an assessment of damages. (*Lynch v. Precision Machine Shop, Ltd.* (1982), 93 Ill. 2d 266, 278.) The general rule of damages in a tort action is that "the wrongdoer is liable for all injuries resulting directly from the wrongful acts ***, provided the particular damages are the legal and natural consequences of the wrongful act imputed to the defendant, and are such as might reasonably have been anticipated. Remote, contingent, or speculative damages do not fall within this general rule." *Siemieniec v. Lutheran General Hospital* (1987), 117 Ill. 2d 230, 259.

Regarding medical expenses, Howmedica argues that the $21,000 attributable to the revision surgery was nonrecoverable because the evidence undisputedly reveals that the plaintiff would have had to undergo another revision surgery at some point. Dr. Simmons testified, however, that, had the initial knee device lasted as long as anticipated – approximately 10 years according to Simmons and as long as 18 years according to Dr. Bloebaum – only one revision surgery would have been necessary in the plaintiff's lifetime. Because the first device failed in less than three years, the evidence reveals that multiple revision surgeries might have been necessary. The trial court was well within its discretion to compensate the plaintiff for the expense of an additional revision he would not otherwise have had to face had the initial device not failed.

We likewise conclude that it was within the trial court's discretion to award the plaintiff lost wages of approximately $400,000. The evidence indicates that, at the time of the initial surgery, the plaintiff was 46 years old and had been consistently employed in the same job for nearly 20 years prior to that. There was no evidence presented that the plaintiff would not have worked to retirement age had he been able to do so. At the time of the surgery, the plaintiff was earning $25,000

per year. As previously stated, the plaintiff presented evidence demonstrating that a nondefective knee device could last as long as 18 years. In light of this evidence, the trial court could well have concluded that the plaintiff lost 16 years' of income by having to undergo revision surgery several years sooner than anticipated. We do not believe an award of $400,000 for lost wages was manifestly erroneous.

The remainder of the damages award was for the plaintiff's pain and suffering, disability and disfigurement, and future medical expenses. The dissent contends that the amounts awarded for pain and suffering and for disability and disfigurement are "grossly excessive" and should be reduced. While it is unclear from the record precisely how much of the $1.69 million award the trial court allocated to these two categories of damages, the dissent estimates that it was between $1 million and $1.2 million. Even if that is the case, we do not agree that such an award is "grossly excessive." To the contrary, we believe the damages awarded are amply supported by the evidence.

While we are cognizant of the fact that the failed device did not *cause* the plaintiff's original knee injury, we nevertheless find that it was responsible for a substantial portion of the pain, suffering, disability and disfigurement the plaintiff experienced from the spring of 1988, when the device failed, onward. As the evidence reveals, both the plaintiff and his doctor fully anticipated that the plaintiff would be able to return to work following the initial knee surgery. He, in fact, did so one year later. After the device failed, however, the plaintiff was unable ever to return to the job he had performed for nearly 20 years or to any other job, and his activity level outside of work was also severely curtailed. Had the device functioned as intended, the plaintiff could have lived at least five and as many as 15 or 16 years longer, according to Dr. Simmons, without the disability and disfigurement which flowed from the device's failure. We hold that the trial court did not manifestly err in awarding the damages it did for the plaintiff's disability and disfigurement.

Moreover, ample evidence was presented at trial showing that the plaintiff endured a significant degree of physical and mental suffering beginning as early as 2½ years after the initial surgery, when his knee

began to pop and swell and become unstable. To alleviate these symptoms, the premature revision surgery had to be performed. However, that surgery was unsuccessful in eliminating the physical problems which occurred when the first device failed. In fact, at the time of trial, which followed four years after the second surgery, the plaintiff still complained of pain, stiffness, swelling and instability in his knee. While we agree with defendants that pain, swelling and other physical signs leading to the necessity for revision knee surgery occur regardless of *when* a device wears out, the fact is that the revision surgery in this case was forced to occur several years earlier than it should have been, causing the plaintiff to experience unanticipated suffering during a time in which the initial knee device should have improved his condition. Moreover, while we acknowledge Dr. Simmons' testimony that the plaintiff was better off having had the second surgery, it is difficult to imagine how he would not have been, given that the failure of the first device led to popping and snapping inside his knee joint and caused a significant amount of pain, swelling, and instability in his knee.

Moreover, the evidence shows that, because of the premature failure of the knee device, the plaintiff in all likelihood would have had to undergo an additional surgery in his lifetime that would have been avoided had the initial knee device functioned for as long as expected. Apart from the physical pain another surgery would bring, Dr. Simmons testified, a third surgery would have caused the plaintiff's knee to become even more unstable and would have exposed the plaintiff to further risks of infections, nerve damage, and vessel injury.

This court has held in the past that a damages award for pain and suffering is proper where them is evidence of a physical injury. (See *Ballweg v. City of Springfield* (1986), 114 Ill. 2d 107, 116.) In light of the consequences flowing from the premature failure of the Howmedica knee device, as discussed above, we uphold the award of damages for the plaintiff's pain and suffering.

D. Lukens' Liability

Finally, the defendants contend that the appellate court erred in finding that they waived their argument that the trial court's judgment against Lukens should be reversed based on insufficient evidence. The

appellate court applied the waiver rule after determining that the defendants failed to raise the issue regarding Lukens' liability in its initial brief. The defendants maintain that the issue was sufficiently raised in their brief. We are unable to determine the propriety of the appellate court's ruling on this issue, however, because the defendants have failed to support their argument with adequate proof. Specifically, the record before us does not contain the defendants' initial brief filed in the appellate court. On review, the appellant has the burden of presenting the court with an adequate record regarding the claimed error (*Holston v. Sisters of the Third Order of St. Francis* (1995), 165 Ill. 2d 150, 163), and any doubts which may arise from the incompleteness of the record will be resolved against the appellant (*Foutch v. O'Bryant* (1984), 99 Ill. 2d 389, 391-92). In the absence of the proof necessary to resolve the issue, we must presume that the appellate court's determination was proper.

CONCLUSION

For the foregoing reasons, the judgment of the appellate court is affirmed.

Affirmed.

JUSTICE HARRISON took no part in the consideration or decision of this case.

JUSTICE MILLER, concurring in part and dissenting in part:

I agree with the majority's holdings that defendant Howmedica, Inc., waived its preemption defense and, further, that them was sufficient evidence to find Howmedica strictly liable for the plaintiff's injuries. I do not agree, however, with the majority's conclusion that the amount of damages awarded in this case is supported by the record.

In closing argument, plaintiff's counsel requested a damage award ranging between $1.6 million and $1.8 million, divided among the following: $200,000 for past and future medical expenses, $400,000 for past and future lost wages, $500,000 to $600,000 for pain and suffering, and $500,000 to $600,000 for disability and disfigurement. The trial judge apparently agreed with counsel's itemization, for, in a bench proceeding without a jury, the judge awarded nearly $1,690,000 in damages, a sum that approximates plaintiff's request.

I believe that the amount of damages awarded by the trial judge is against the manifest weight of the evidence. In upholding the present award, the appellate court concluded, from the testimony of the plaintiff's own doctor, that the plaintiff might have lost seven years of employment as a consequence of the premature failure of the prosthesis at issue here. The plaintiff earned approximately $25,000 a year from his employment as a truck driver and laborer, so the amount of lost income according to his best estimate, even without discounting it to present value, would have been about $175,000, far less than the $400,000 urged by counsel.

An award of $200,000 for past and future medical expenses similarly lacks support in the record. The estimated expenses of a revision surgery are about $30,000. Although the premature failure of the plaintiff's prosthesis could necessitate earlier replacements in future years, a sum as large as $200,000 for medical expenses is at best speculative under the facts in this case.

Finally, one must question an award totaling more than $1 million for pain and suffering and disability and disfigurement. Plaintiff is entitled to be compensated only for the injuries attributable to the premature failure of the prosthesis involved here. Even if one allows that the failure of the device would accelerate the normal replacement schedule, I fail to see how the pain and discomfort, or disability and disfigurement, from the added procedures caused by that can justify an award of more than $1 million, the amount apparently determined here. For these reasons, I believe that the award of damages in this case is not supported by the record, and I would remand the action to the circuit court for further proceedings on this issue.

JUSTICE HEIPLE, dissenting:

"Little Jack Horner
Sat in the corner,
Eating a Christmas pie;
He put in his thumb,
And he took out a plum,
And said, 'What a good boy am I!'"

Plaintiff sought damages against defendants, Howmedica and its sales representative, for injuries caused by the premature failure of the

artificial knee manufactured by Howmedica. Defendants argued that provisions of the United States Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. §301 *et seq.* (1970)) preempted plaintiff's State-law tort claim. The majority determined, and I concur, that defendants waived their preemption argument by failing to raise it in the trial court.

I disagree, however, with the court's affirmance of the damage award. In truth, the damages awarded to plaintiff by the trial court are grossly excessive and should be reduced.

Plaintiff, then age 45, injured his knee at work in 1983. After other treatment options failed, plaintiff decided to undergo total knee replacement. In 1985, Howmedica's artificial knee was implanted and plaintiff's doctor related his hope that it would last 8 to 12 years. About three years later, however, plaintiff's Howmedica knee failed and it was successfully replaced with another Howmedica artificial knee. Plaintiff then brought a products liability suit against Howmedica and a negligence suit against Howmedica's sales representative. After a bench trial, plaintiff was awarded damages of $1,686,988.70.

To award such an excessive sum, the trial court either forgot or did not care that plaintiff's knee was not injured by defendants' device, but had been damaged years earlier in a work-related injury. The only valid complaint against defendants is that the artificial knee wore out sooner than the parties had hoped.

In closing argument, plaintiff argued that a proper damage award was $1.6 to 1.8 million, apportioned as: $200,000 for past and future medical expenses; $400,000 for past and future lost wages; $500,000 to $600,000 for pain and suffering; and $500,000 to $600,000 for disability and disfigurement. Since the trial court awarded almost $1.69 million, an amount in the range suggested by plaintiff, it may be assumed that the individual awards were broken down as plaintiff suggested.

PAIN AND SUFFERING

The trial court awarded plaintiff over $500,000 for pain and suffering. Since defendant's device did not cause plaintiff's original knee injury, plaintiff is entitled to pain and suffering damages only for affliction caused by the premature failure of defendant's device. At the

time of trial, plaintiff's knee revision was doing fine and he was on no prescription pain medication. In addition, he had not seen the doctor in the 18 months prior to trial, other than during a routine yearly check-up. Such evidence does not support a damage award in excess of half a million dollars for pain and suffering.

DISABILITY AND DISFIGUREMENT

Plaintiff received more than $500,000 for disability and disfigurement. As stated above, plaintiff is entitled to damages only for the disability and disfigurement that resulted from the premature failure of defendant's device.

After plaintiff's initial knee injury at work, he was disabled from many activities. Once his knee was replaced by the Howmedica knee, plaintiff was able to be more active, but was still restricted from heavy lifting. At that time, plaintiff's doctor rated him as having a 50% disability for purposes of worker's compensation.

Following failure of the Howmedica knee and the necessary revision surgery, plaintiff suffered from various disabilities, including limitations on boating, golf, and gardening. However, plaintiff is not entitled to damages for these restrictions because they existed prior to the implantation of the Howmedica knee and were not caused by its premature failure. Indeed, plaintiff's doctor testified that plaintiff was better off after surgery than if he had never had knee replacement surgery.

Once again, this court refuses to reign in the riverboat gambling atmosphere that characterizes the Illinois tort system. See *Lee v. Chicago Transit Authority* (1992), 152 Ill. 2d 432, 480 (Heiple, J., dissenting) ("While the courts could order remittitur in an appropriate case such as [this], they have shown no willingness to do so").

Justice demands that plaintiff's damages should be subject to a substantial remittitur. Accordingly, I respectfully dissent.

APPENDIX B - OPINION OF THE ILLINOIS APPELLATE COURT DATED NOVEMBER 14, 1994

MARILYN HAUDRICH, as Executor and Sole Legatee of Donald Haudrich, Deceased,
Plaintiff-Appellee,
v.
HOWMEDICA, INC., and MICHAEL LUKENS,
Defendants-Appellants.

No. 5-92-0863.

Nov. 14, 1994.

James V. O'Brien, Thomas L. Caradonna, Lewis, Rice & Fingersh, St. Louis, MO, for appellants.

Thomas Q. Keefe, Jr., P.C., Thomas Q. Keefe, Jr., Cook, Shevlin, Ysursa, Brauer & Bartholomew, Ltd., Harriet H. Hamilton, Belleville, for appellee.

Justice CHAPMAN delivered the opinion of the court:

In November 1985 Dr. Simmons inserted a Howmedica knee implant into Donald Haudrich and told him it should be good for approximately 10 years. Three years later the implant failed, and Dr. Simmons successfully inserted another, different type of Howmedica knee, but Donald could not return to work. Donald sued Howmedica, the manufacturer, on a product liability theory, and after a bench trial, Donald was awarded $1,686,988.70. (Donald died during this appeal, and Marilyn Haudrich has been substituted as plaintiff. Both will be referred to as plaintiff.)

The only issue we will address in this opinion is whether this product liability claim is preempted by the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. We conclude that there is no preemption of this claim. Neither the statute involved nor its legislative history nor the regulations promulgated under the authority of the statute supports a claim of preemption under

the United States Supreme Court's consensus of rules for analyzing such claims. (Cipollone v. Liggett Group, Inc. (1992), 505 U.S —, 112 S.Ct. 2608, 120 L.Ed.2d 407.) The preemption doctrine in tort cases has been raised only relatively recently. (Foote, Administrative Preemption: An Experiment in Regulatory Federalism, 70 Va.L.Rev. 1429, 1430 (1984) (Administrative Preemption).) Commentators have offered different reasons for its late arrival on the legal scene. Some have suggested that respect for federalism has protected the States' court systems from intrusion in an area that has been recognized as a matter for local rather than Federal law since the inception of the nation. (Winokur & Robbins, Consumer Product Safety: Preemption, The Commerce Clause & State Regulatory Authority, 25 Vill.L.Rev. 232.) Others have suggested that parties' concerns about federalism are pendulum-like and swing from a desire for no intrusion to a prayer for full preemption depending upon which side feels preemption will be beneficial to its position. (Administrative Preemption, 70 Va.L.Rev. at 1466.) Regardless of the reasons for the doctrine's prepubescent involvement in the tort field, it has existed long enough for litigation with claims of preemption to reach the United States Supreme Court.

In Cipollone v. Liggett Group, Inc. (1992), 505 U.S. —, 112 S.Ct. 2608, 120 L.Ed.2d 407, the Supreme Court addressed the defendant's claim of preemption, which was based on the Federal Cigarette Labeling and Advertising Act of 1965 (Act) and its 1969 amendments. Although Justice Stevens wrote for the plurality, a rearrangement of the three opinions serves to highlight the agreement on certain rules that are shared by all the justices.

Justices Kennedy, Souter, and Blackmun concurred in part because they agreed that the 1965 Act did not preempt tort claims against cigarette manufacturers, and they dissented in part because they concluded that its 1969 amendments also did not preempt.

Justices Scalia and Thomas also concurred in part and dissented in part. They dissented because they thought that both the 1965 Act and its 1969 amendments preempted all such tort claims, but they agreed with Justice Stevens' relation of most of the rules for the determination of preemption claims. The Scalia-Thomas dissent disagreed with the other seven justices on only one of its stated rules:

"[T]he pre-emptive scope of the 1965 Act and the 1969 Act is governed entirely by the express language in § 5 of each Act." (Emphasis added.) (Cipollone, 505 U.S. at —, 112 S.Ct. at 2618, 120 L.Ed.2d at 423.)

Therefore, on the express-language point, seven of the nine members of the Supreme Court are in agreement, and on the other rules for determining preemption, all nine are in agreement.

What then are the rules governing the resolution of preemption claims that are agreed upon by all nine members of the Court?

(1) "Consideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded * * * unless that [is] the clear and manifest purpose of Congress.'" (Emphasis added.)

(2) Perhaps a corollary to number 1, but separately stated, " ' "The purpose of Congress is the ultimate touchstone" ' of pre-emption analysis. [Citations.]" (Emphasis added.)

(3) There is a "presumption against the preemption of state police power regulations."

(4) Perhaps as a corollary to number three's presumption, but separately stated, "This presumption reinforces the appropriateness of a narrow reading * * *."

(5) The fact "[t]hat Congress requires a particular warning label does not automatically pre-empt a regulatory field."

(6) "There is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law damage actions."

(7) Common law damage actions can impose requirements. Cipollone, 505 U.S. at — - —, 112 S.Ct. at 2617-20, 120 L.Ed.2d at 422-26.

The Blackmun-Kennedy-Souter concurrence supplies an addendum to number seven, and as this addendum is neither rejected nor criticized by any of the other opinions, it is also presumably agreed upon by all nine members of the court.

> "The principles of federalism and respect for state sovereignty that underlie the Court's reluctance to find preemption where Congress has not spoken directly to the issue apply with equal force where Congress has spoken, though ambiguously. In such cases, the question is not whether Congress intended to pre-empt state regulation, but to what extent. We do not, absent unambiguous evidence, infer a scope of preemption beyond that which clearly is mandated by Congress' language. I therefore agree with the Court's unwillingness to conclude that the state common-law damages claims at issue in this case are preempted unless such result is ' "the clear and manifest purpose of Congress." ' " (Emphasis in original.) Cipollone, 505 U.S. at —, 112 S.Ct. at 2626, 120 L.Ed.2d at 433 (Blackmun, J., concurring in part and dissenting in part, joined by Kennedy and Souter, JJ.).

This compilation of the rules relied upon by the Supreme Court in one of its more recent rulings on the preemption issue makes two things clear. One, case law can constitute a requirement which can be barred by the preemption doctrine. Two, in order for case law to constitute such a requirement and to invoke preemption, it must be abundantly clear that Congress intended that result.

In addition to the general principles laid down in Cipollone, we think it is significant that the Justice Stevens opinion largely based its conclusions of no preemption for the 1965 Act and preemption for the 1969 amendment on the differences in wording. The 1965 Act provided in part:

> "(a) No statement relating to smoking and health, other than the statement required by section 4 of this Act, shall be required on any cigarette package.
> (b) No statement relating to smoking and health shall be required in the advertising * * *." (Emphasis added.) (Federal Cigarette Labeling and Advertising Act, Pub.L. 89-92, 79 Stat. 282, as amended, 15 U.S.C.A. secs. 1331-40 (West 1982).)

Justice Stevens concluded that "[section] 5 of the 1965 Act only preempted state and federal rulemaking bodies from mandating particular cautionary statements and did not pre-empt state law damages actions." (Cipollone, 505 U.S. at —, 112 S.Ct. at 2619, 120 L.Ed.2d

at 425.) Justice Stevens then compared the 1965 Act with the 1969 amendment, which provided:

> "No requirement or prohibition based on smoking and health shall be imposed under State law with regard to the advertising * * *." (Emphasis added.) (Public Health Cigarette Smoking Act of 1969, Pub.L. 91-222, 84 Stat. 87, as amended, 15 U.S.C.A. §§ 1331-40 (West 1982).)

Justice Stevens concluded that the emphasized language, among other things, warranted extending preemption to State damage actions. This comparison and conclusion is significant because, even though the Medical Device Amendments preemption provision does not mirror either the 1965 Act or the 1969 amendment, it is certainly closer in tenor to the 1965 Act.

With these principles in mind, we turn first to an examination of the statute involved in this case.

STATUTE

[1][2] Section 360k of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act provides:

> " § 360k State and local requirements respecting devices (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision * * * may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.
>
> (b) Exempt requirements
>
> Upon application of a State or a political subdivision thereof, the Secretary may * * * exempt from subsection (a) * * * a requirement of such State or political subdivision * * * if
>
> (1) the requirement is more stringent * * *; or
>
> (2) the requirement–
>
> (A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement *635 under this chapter." (Bold deleted; emphasis added.) 21 U.S.C.A. sec. 360k (West 1994 Supp.).

The first point to be made based on the statute's language requires a comparison of the opening sentences of the opening paragraphs of section (a), the general rule, and section (b), the exemption section.

Section (a) provides:
"[N]o State or political subdivision of a State may establish * * * any requirement * * *."

Section (b) provides:
"Upon application of a State or a political subdivision thereof, the Secretary may * * * exempt a requirement * * *."

The same emphasized phrase is used in each section, but the action contemplated by that phrase effectively excludes courts. Why? Because, although it has been held that courts are capable of establishing requirements by imposing damage awards (*San Diego Bldg. Trades Council v. Garmon*, (1959), 359 U.S. 236, 79 S.Ct. 773, 3 L.Ed.2d 775), a capability that could qualify courts as actors under section (a), it has never been held that courts can apply for exemption to the Secretary of Health, Education, and Welfare or to any other person or entity. Because courts are neither legally nor practically capable of applying for exemptions and, therefore, cannot come within the definition of "State or political subdivision" of section (b), it would certainly be anomalous to include them in the identical definition under section (a). If courts cannot be incorporated into the phrase "State or political subdivision," then they cannot be the source of "requirements" that are preempted.

Further, the use of the phrase "State or political subdivision" suggests positive requirements (i.e., statutes, ordinances, or regulations), and not case law, because political subdivisions such as counties and cities do not have the power to hand down case law. Although it could be argued that "State" could include the courts of the State, if such a broad construction is to be given that word, then it is obvious that "State" could also include political subdivisions of the State. Since words in a statute must be construed to have some

meaning and purpose, i.e., to be nonsuperfluous (Platt v. Union Pacific R.R. Co. (1879), 99 U.S. 48, 25 L.Ed. 424; Hirschfield v. Barrett (1968), 40 Ill.2d 224, 239 N.E.2d 831, the words political subdivision must mean something, and obviously they mean what the words ordinarily mean. (See also the discussion under REGULATIONS, infra.) Their inclusion strongly suggests that Congress' use of the term "requirement" meant a requirement imposed by statutory authority and not by case law.

The second emphasized phrase, "establish or continue in effect * * * a requirement," also suggests that Congress intended "requirement" to refer to statutes, ordinances, or regulations, all of which can be established or continued in effect. Case law is handed down, developed, or decreed, but it is not "established or continued in effect."

Not only does the language in the emphasized portions of subsection (a), the general rule, support the idea that Congress did not intend to preempt common law decisions, but the emphasized wording of subsection (b), exempt requirements, supports the same conclusion. An unstrained reading of "the Secretary may exempt * * * a requirement of such State or political subdivision" leads to the conclusion that statutes, ordinances, or regulations are what "requirement" is describing; Secretaries do not normally exempt court decisions.

A call for an unstrained wording of the statute is not the only basis for concluding that "requirement" does not include case law. Recall that in this context the statute is speaking of exempting requirements of State and political subdivisions. When we turn from the words of the statute to the actions of the Commissioner of the Food and Drug Administration (FDA) (who is authorized to grant these exemptions (21 C.F.R. sec. 808.1)), we discover that 21 States and the District of Columbia have sought exemptions from section 360k's preemption doctrine. More importantly, although the Commissioner granted exemptions in each of the 22 instances that exemptions were sought, there have been no exemptions sought or granted that deal with court decisions. This null set of exemptions for court decisions strongly suggests that the unstrained interpretation of "requirement" is the appropriate one.

The final point to be made based on the wording of section 360k itself is the repeated use of the word "requirement" to designate both the actions taken, or to be taken, by Congress and/or the FDA and any future actions to be taken by States or political subdivisions. In both section 360k(a), the general-rule-of-preemption provision, and section 360k(b), the exemption-from-preemption section, Congress used the language "requirement applicable under this chapter" when referring to action to be taken by it and the FDA. Any action taken by Congress or the FDA would of necessity be in the form of statutes or regulations. To state the obvious, Congress legislates; the FDA regulates; but neither Congress nor the FDA can adjudicate. Therefore, Congress' use of the term "requirements" not only to describe actions taken by it and/or the FDA but also to describe actions taken by "State or political subdivisions" leads to the conclusion that a "requirement" in the latter context will be imposed by either a legislative or regulatory agency, and the corollary of that conclusion is that "requirement" in this context does not mean something imposed by a court.

LEGISLATIVE HISTORY

Turning from the wording of the statute to its legislative history, we find three indications that Congress did not intend to preempt tort litigation in this country when it passed the 1976 Medical Device Amendments. First, the primary purpose of the 1976 Medical Device Amendments was "to assure the reasonable safety and effectiveness of medical devices intended for human use." (D. O'Keefe & R. Spiegel, An Analytical Legislative History of the Medical Device Amendments of 1976, Appendix II at 51 (1976) (An Analytical Legislative History).) If safety promotion was Congress' primary purpose, it would be strange for Congress to eliminate the safety aspects inherent in tort litigation (W. Prosser, Handbook of The Law of Torts, sec. 5, at 23 (4th ed. 1971); Prentice & Roszkowski, "Tort Reform" and the Liability "Revolution": Defending Strict Liability in Tort for Defective Products, 27 Gonz.L.Rev. 251 (1991-92)) by destroying tort litigation in the entire country with the same statute it passed to promote safety. It would be stranger still for Congress to take such a dramatic action without even mentioning it as a consequence of the passage of a bill that was debated for years. Yet the debate and Congressional record are

barren of any indication that Congress intended to preempt court decisions by passing the 1976 Medical Device Amendments.

The second indication of a lack of intent to preempt is found in the Committee Report:

> "The Committee recognizes that if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened. For this reason the reported bill contains special provisions (new section 521 of the Act) governing regulation of devices by States and localities." (Emphasis added.) (An Analytical Legislative History, Appendix III at 45.)

The emphasis on jurisdiction and localities is to highlight that the committee's concern was over requirements imposed by the types of entities discussed earlier, States, counties, and municipalities, and not by courts.

The third basis of the conclusion is afforded by the only example given in the legislative history of a requirement "imposed by jurisdictions other than the Federal government," California's 1970 Sherman Food, Drug, and Cosmetic Law. In fact, the Committee used the California statute as an example of a "requirement":

> "In the Committee's view, requirements imposed under the California statute serve as an example of requirements that the Secretary should authorize to be continued * * *." An Analytical Legislative History, Appendix III at 46.

The fact that the only example given in the legislative history is that of a California statute strengthens by implication the first basis. If Congress thought a California statute worthy of comment as an example of a requirement, how much more significant is it that Congress did not indicate that it considered court decisions to be within the realm of requirements?

REGULATIONS

Turning from the language of the statute and its legislative history to the language of the regulations promulgated to explain and implement the statute, we first examine some basic definitions. Political subdivision is defined as "any lawfully established local governmental

unit" that has "the authority to establish or continue in effect any requirement * * *." (21 C.F.R. sec. 808.3(d).) Although "local governmental unit" is not defined by the regulations, Black's Law Dictionary supplies a definition of "local government":

"City, county, or the governing body at a level smaller than a state. Local government has the greatest control over real property, zoning and other local matters." (Black's Law Dictionary 939 (6th ed. 1990).) These definitions make it clear that Congress and the Commissioner were not contemplating courts as the source of requirements under section 360k. This interpretation is strengthened by an examination of the definition of "compelling local conditions," which "includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographical area or population of the State or political subdivision * * *." (21 C.F.R. sec. 808.3(b).) Courts exist to resolve disputes, and the resolutions of these disputes do not depend upon "factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population * * *." Therefore, the definitions of both "political subdivision" and "compelling local conditions" support the idea that courts were not intended to be within the class of entities that establish requirements. Obviously, if courts are not within the class of entities that establish requirements, court decisions are not within the class of entities whose decisions are preempted by section 360k.

The next portion of the regulations that militates against the inclusion of courts within the class of those which create requirements is section 808.5, "Advisory Opinions." Subsection (a) provides:

> "(a) Any State, political subdivision, or other interested person may request an advisory opinion with respect to [preemption matters]." (21 C.F.R. sec. 808.5(a).)

Although it might be quite helpful to a State, county, or city to have the Commissioner's input on whether its requirement would be preempted, and therefore it might be appropriate for any or all of those entities to seek an advisory opinion from the Commissioner, it would be absolutely inappropriate for a court to make such a request. This implicit exclusion of courts from the contemplated actions of States and political subdivisions also eliminates courts as a source of requirements and excludes their decisions from preemption.

> This exclusionary rationale finds further support in section (b): "The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations * * *.
>
> (2) A proposed state or local requirement * * * is not eligible for exemption from preemption * * *." (Emphasis added.) (21 C.F.R. sec. 808.5(b).)

Two aspects of this quotation strengthen the conclusion that courts were not included within the class of those whose acts would be preempted. First, a Commissioner's advisory opinion to a court on an issue that is before the court would be an improper communication and is, therefore, not likely to be what the Commissioner had in mind when the regulation was promulgated. Second, section (b)(2) refers to "proposed * * * requirement," and courts do not issue "proposed" requirements; they render final decisions.

When we move from the regulations' definition and advisory-opinion provisions to their explanation of the exemption procedures, we discover some extremely telling terms. Section 808.20(a) provides:

> "(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement." (Emphasis added.) (21 C.F.R. sec. 808.20(a).)

The use of the word "enacted" can only refer to requirements passed by legislative bodies, not to decisions issued by courts. If it were to be contended that courts do "issue" opinions, there are three indications within this section that weigh against such a contention. First, "issued" can also refer to regulations and ordinances. Second, the word issued is third in the series of "enacted, promulgated or issued," and the first two clearly refer to legislative and/or regulatory methods. When two or more words of analogous meaning are employed together in a statute they are understood to express the same relation (People v. Goldman (1972), 7 Ill.App.3d 253, 255, 287 N.E.2d 177, 179); therefore, the

word "issued" should be considered as of the same type as "enacted and promulgated" and, therefore, legislative or regulatory. Third, there is a reference to "the effective date of the requirement." Generally, only legislative and regulatory pronouncements have any concern about effective dates.

Moving from subsection (a) to subsection (c) of section 808.20, we find the Commissioner calling for certain materials to accompany an application for an exemption, among which are

> "(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance in final form [and] [i]f the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations." (21 C.F.R. sec. 808.20(c).)

Perhaps the clearest indication of all is the first phrase of section (c)(1), "a current copy of any statute, rule, regulation or ordinance * * * considered * * * to be a requirement * * *." Every item in the series is legislative or regulatory; there is absolutely no reference to, or indication of, any intent to include court decisions as a source of requirements. If any buttressing of this position is needed, it is found in the last sentence of section (c)(1), which refers to judicial interpretations of the requirements.

Finally, subsection (c)(5) requires identification of:

> "(5) The title of the chief administrative or legal officers of that State or local agency that has primary responsibility for administration of the requirement." (21 C.F.R. sec. 808.20(c)(1).)

State and local agencies administer requirements; courts do not.

The final section of the regulations that we shall examine is the only one that offers support for defendants' position, but before quoting that portion of the regulation (21 C.F.R. see. 808.1(b)), we will first examine another, and contradictory, portion of the same regulation (21 C.F.R. sec. 808. 1(d)(6)(ii)), which provides in part:

> "In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute * * *." (Emphasis added.) (21 C.F.R. sec. 808.1(d)(6)(ii).)

Again, the Commissioner has equated the term "requirement" with a statute, not with a court decision.

The Secretary departs from this continuous and consistent treatment of requirement as synonymous with either legislative or regulatory pronouncements, and not with judicial acts, on only one occasion, the portion of section 808.1(b) mentioned earlier, which provides:

> "[N]o State or political subdivision may establish or continue in effect any requirement * * * (whether established by statute, ordinance, regulation, or court decision), * * *." (Emphasis added.) (21 C.F.R. sec. 808.1(b).)

The emphasized phrase, "or court decision," clearly supports defendants' position that the Commissioner intended to preempt judicial decisions under the 1976 Medical Device Amendments, and it is the wording that has been relied upon by at least one court. (See Mendes v. Medtronic, Inc. (1st Cir.1994), 18 F.3d 13; King v. Collagen Corp., (1st Cir.1993), 983 F.2d 1130; Stamps v. Collagen Corp. (5th Cir.1993), 984 F.2d 1416; Covey v. Surgidev Corp. (N.D.Ohio 1993), 815 F.Supp. 1089). But see Kociemba v. G.D. Searle & Co. (D.Minn.1988), 680 F.Supp. 1293; Larsen v. Pacesetter Systems, Inc. (1992), 74 Haw. 1, 837 P.2d 1273, modified on motion for reconsideration (1992), 74 Haw. 650, 843 P.2d 144.) The problem with the parenthetical language is that it is contrary to every other expression by the FDA on this point, including the administration's statements published at the time of the adoption of the regulation in which it repeatedly refers to "State and local governments," "State or local legislative body," "State statutes," "State provision," and a "State or local provision" (43 Fed.Reg. 18661, 18662-64 (May 2, 1978)) and, equally important, in which it nowhere refers to court decisions as being within the preempted area. We cannot conclude, under these circumstances, that preemption of common law actions is mandated.

We have spent some time in setting forth the multiple statements that belie the Commissioner's solitary inclusion of judicial decisions, because of the importance of the issue of federalism. The weakness of the central government under the Articles of Confederation precipitated the calling of the constitutional convention, but the framers' experiences in the then-recent revolution had created memories that cautioned the States against relinquishing too much control. As always when two competing principles are compressed into a compromise, stress survived.

This stress was the subject of judicial action during the country's early years (Gibbons v. Ogden (1824), 22 U.S. (9 Wheat) 1, 6 L.Ed. 23), and on one occasion became so great that the ever-present potential conflict between the central government and the States erupted into war. Although the Civil War resolved the most catalytic of the circumstances underlying Federal-State tensions, cases that called for resolution of these tensions continued to arise. (Gulf, C. & S. F. Ry. Co. v. Hefley (1895), 158 U.S. 98, 15 S.Ct. 802, 39 L.Ed. 910.) In most of these cases, the Court, though not reluctant to enforce the provisions of the supremacy clause, has been conscious of the deference due the States, particularly in areas traditionally reserved to State resolution. It is this deference, coupled with the language of section 360k, its legislative history, and the Commissioner's almost unanimous exclusion of court decisions from the preemption area, that causes us to reject its single inclusion in the area.

With regard to defendants' claim that FDA involvement in the medical-device field insures adequate protection in this area, we note than on November 28, 1990, the Commissioner admitted:

> "[None of the] reviews of pre-1976 devices even began until very recently.
>
> * * * * * *
>
> 98 percent of the estimated 5,000 devices that enter the market every year do so on the basis of a claim by their manufacturer that they are substantially equivalent to an earlier device. In particular, over 80 percent of the devices that are potentially the most dangerous (Class III) enter the market on the basis of a claim by the manufacturer that they are 'substantially equivalent' to a

device already on the market. Although a determination of substantial equivalence involves a review by FDA of what is known of the safety and effectiveness of the devices, and may even include some additional clinical testing, it is not equivalent to an approval by the FDA of the device's safety and effectiveness. Second, the FDA has experienced difficulty in learning about serious problems with devices. The GAO has found that hospitals often do not report potentially hazardous medical devices to the FDA or the manufacturer.

Finally, even when the FDA has discovered a serious health hazard associated with a medical device, the Agency faces a unique barrier to enforcing important administrative remedies. Unlike other health and safety agencies, FDA may not take administrative action to order a defective device recalled unless it can show that the device did not meet the 'state-of-the-art' at the time it was designed and manufactured." H.R.Rep. No. 101-808, 101st Cong., 2d Sess. (1990) U.S.Code Cong. & Admin.News 1990, pp. 6305, 6307.

The apparent inability of the agency to investigate, to issue approval, and to monitor compliance suggests that it should not be the sole source of protection for the consumers of this country. In fact, it seems almost a perversion of the protective principle to suggest that laws such as the 1976 Medical Devices Amendments, whose purpose is to assure the "safety and effectiveness of medical devices intended for home use" (H.R.Conf.Rep. No. 94-1090, 94th Cong., 2d Sess., at 51 (1976), U.S.Code Cong. & Admin.News 1976, pp. 1070, 1103, cited in An Analytical Legislative History, Appendix II at 51), destroyed in one stroke all the potential safety benefits of all tort litigation in all 50 states.

As strange as such an action might seem to some, we agree that the Constitution's supremacy clause gives Congress the power to do just that. But we cannot agree that a single statement by the Commissioner, a statement that goes well beyond the statute itself and is contrary to every other regulation promulgated by that same Commissioner, reflects "the clear and manifest purpose of Congress." Cipollone, 505 U.S. at —, 112 S.Ct. at 2617, 120 L.Ed.2d at 422.

If the framers' concern with the stresses of compromise and the nation's convulsive upheaval of resolution are to be given their appropriate meaningfulness, if the common law claims of two hundred years are to be curtailed, if the courts of the States are to be deprived of deciding the cases that have been their historical province, if the supremacy clause is to mean preemption uber alles, then let the execution of the tort system be public. Let the sword of supremacy be wielded by Congress in the full light of day; let not its death be dealt in the dark, let it not be bled dry by a bureaucrat's blade.

We conclude that Congress did not intend to preempt common law decisions by passing the 1976 Medical Device Amendments. Even if we were to assume that Congress and the Commissioner intended to preempt common law decisions in this area, both the statute and the regulation defendants rely upon to support preemption contain exceptions to preemption. As indicated earlier, subsection 360k(b) allows the secretary to exempt requirements from preemption. Section 808.1 parallels the statutory language and then amplifies it:

> "(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are specific requirements applicable * * *, thereby making any existing divergent State or local requirements * * * different from, or in addition to, the specific Food and Drug Administration requirements." (Emphasis added.) 21 C.F.R. sec. 808.1(d).

Finally, the FDA has also endorsed this conclusion. In its explanatory statements published at the time of the adoption of the regulations, it states:

> "Thus, from a plain reading of section 521 of the act it is clear that the scope of preemption is limited to instances where there are specific F.D.A. requirements applicable to a particular device * * *." (Emphasis added.) 43 Fed.Reg. 18662 (May 2, 1978).
>
> "There is nothing in the legislative history to indicate Congress intended that the amendments should result in less protection for the public which would be the natural consequences of State Controls being eliminated during the considerable period of time it will take for F.D.A. to implement fully the new authorities

provided in the Amendments." (Emphasis added.) 43 Fed.Reg. 18663 (May 2, 1978).

In this case defendants presented no evidence of any specific counterpart regulation or any other specific requirement that would have preempted the court's decision. Since defendants have the burden of proof on the issue of preemption, and since no evidence was presented to establish a specific requirement, defendants have failed to meet its burden of proof on the issue.

There are other important issues raised by defendants, but they will of necessity be addressed in an unpublished portion of this disposition. See Supreme Court Rule 23(c)(2) (Official Reports Advance Sheet No. 15 (July 20, 1994), eff. July 1, 1994).

UNPUBLISHED TEXT FOLLOWS

[The following material is nonpublishable under Supreme Court Rule 23.]

In view of our conclusion that section 360k does not preempt common law claims, we need not discuss plaintiff's contentions that: (1) defendants waived any preemption claim by failing to raise it at trial, and (2) defendants' claim of preemption was without merit because it was based on a market approval that was received almost three years after the implant was inserted. We will, however, address the other issues raised by defendants, and for those issues a more detailed statement of facts may be helpful.

Plaintiff, 45-year-old Donald Haudrich, suffered a work-related injury to his left knee, necessitating a total joint replacement. Dr. Simmons, the doctor who performed the surgery, told Haudrich that the knee prosthesis would last approximately 10 years, give or take two years. Plaintiff's knee failed approximately three years after the implantation, and he had to undergo revision surgery. Plaintiff filed a products liability action against the manufacturer of the knee prosthesis, Howmedica, Inc. (Howmedica), and Michael Lukens, a Howmedica sales representative. The trial court awarded $1,686,988.70 in damages. Defendants appeal.

Defendants argue that there was insufficient evidence to support a finding that plaintiff was injured by an unreasonably dangerous

condition of the prosthesis. A product's injury-causing condition can be anything that causes the product to fail to perform in the manner reasonably expected in light of its intended nature and function. (Dunham v. Vaughan & Bushnell Manufacturing Co. (1969), 42 Ill.2d 339, 247 N.E.2d 401.) A condition or defect in a product is unreasonably dangerous if it subjects those exposed to the product to an unreasonable risk of harm beyond that which is contemplated by the ordinary person with ordinary knowledge common to the community as to the product's characteristics. (See Hunt v. Blasius (1978), 74 Ill.2d 203, 23 Ill.Dec. 574, 384 N.E.2d 368; West v. Deere & Co. (1991), 145 Ill.2d 177, 164 Ill.Dec. 122, 582 N.E.2d 685.) Under the consumer-user contemplation test, whether a product has an unreasonably dangerous design depends on whether the danger resulting from the design is greater than would be contemplated by the ordinary consumer or user. (Hunt, 74 Ill.2d at 211-12, 23 Ill.Dec. at 578, 384 N.E.2d at 372 (citing Restatement (Second) of Torts sec. 402A, comment i (1965)); Lease v. International Harvester Co. (1988), 174 Ill.App.3d 897, 124 Ill.Dec. 340, 529 N.E.2d 57.) Reviewing the testimony is necessary to assess whether there was sufficient evidence to find the product unreasonably dangerous.

Dr. William Simmons, the orthopedic surgeon who performed plaintiff's knee implantation, testified that he first saw Donald Haudrich after Haudrich was injured at work. Simmons described Haudrich as an active 5'11" man, weighing approximately 160 pounds. Simmons' initial physical examination revealed that plaintiff had a slight varus deformity, which is a slight bowleg. Simmons testified that the varus deformity caused more load on the inside of Haudrich's knee and would continue to do so even with the knee prosthesis. When he conducted an arthroscopic investigation of the knee, Simmons discovered that Haudrich had degenerative arthritis. Due to continued pain, difficulty with walking, and the inability to completely extend the knee, Simmons performed a total knee replacement with an uncemented prosthesis on November 10, 1985. Simmons used a Howmedica knee device with a seven-millimeter plastic insert. Dr. Simmons testified that he selected the uncemented procedure because he believed the prosthesis would last longer if the bone could grow into the prosthesis. Simmons testified that, based on what Howmedica representatives told him at seminars

and based on his background and experience, he believed plaintiff's knee replacement would last 10 years, give or take two years.

One year following the surgery, Haudrich was permitted to return to work as a truck driver and occasional laborer. Although his job involved climbing and lifting, Simmons restricted Haudrich to lifting no more than 50 pounds. Approximately one year following surgery, Haudrich complained of instability, swelling, and pain in his knee. Consequently, in January 1989, Simmons performed revision surgery on Haudrich and again inserted a Howmedica knee prosthesis, but this time one with a nine-millimeter plastic insert. Simmons testified that, when he removed the first prosthesis, he found the plastic dish was almost completely worn away and there were multiple shavings of plastic in the back of the knee joint. Simmons testified that the entire plastic portion of the prosthesis failed.

Simmons testified that after the second prosthetic implant Haudrich was permanently restricted from returning to work. Simmons also advised Haudrich against activities involving repeated squatting or bending. Simmons testified that Haudrich can anticipate undergoing revisions in the future because instability increases with each successive revision surgery.

Plaintiff's expert witness, Dr. Roy Bloebaum, holds a Ph.D. in anatomy and is currently employed as a full professor at the University of Utah and the Department of Orthopedic Surgery. For 10 years Bloebaum has analyzed and researched prosthetic implants, particularly the factors that might be inherent in the design of said devices. Bloebaum testified that examination of the prosthetic device in this case revealed delamination, or separation, and pitting and scratching, which are consistent with a design which uses a heat-pressing technique. Bloebaum noted that there was catastrophic failure or a breakage of part of the device, a phenomena which he has observed in other prosthetic devices which employ the heat-pressing technique. He testified that, while the plastic Howmedica uses in the device is the optimum that is available, it is susceptible to fusion defects and sintering defects. Bloebaum testified that these defects can be magnified given the combination of heat pressing, the tibial insert thickness, and contact stresses. He testified that a person's height and weight are factors that

play a role in the survivorship of the implant and that Donald Haudrich's height and weight are good with regards the prospect for survivorship of the implant. He opined that it is not unreasonable for the implant to last 10 to 18 years given a person of Haudrich's height and weight, assuming the prosthesis has no defects.

Bloebaum conceded that proper placement of the device is essential to optimum survivorship of the implant. However, he testified that radiographic analysis of the implant revealed that the prosthesis here was in proper alignment at all times following the implantation in 1985. Bloebaum opined that the device at issue was defective and unreasonably dangerous because the plastic employed is too thin and the heat-pressing process led to its premature failure. Bloebaum testified that in his opinion, to a degree of scientific certainty, drastic premature failure of the device occurred within less than three years of implantation.

Peter Van Syckle, vice president of product development at Howmedica, has a masters degree in mechanical engineering and has participated in the design of the knee prosthesis at issue. Van Syckle testified that, when Howmedica began marketing the device in 1980, the smallest plastic component size was seven millimeters because the physicians wanted to resect a minimum amount of tibia. Van Syckle testified that a design trade-off was necessary because doctors wanted to leave as much of the tibia intact as possible in case later revisions were needed. He stated that it was also desirable to minimize bone loss because bone strength decreases the further you go down the tibia; the support of the prosthesis could be jeopardized if too much bone were removed. Van Syckle testified that the plastic components were heat-polished so that an asymmetrical design could be attained. He testified that the manufacturing technology at the time would not allow for this asymmetry to be machined into the component, and it was in fact more costly to employ a heat-polishing method.

Van Syckle testified that in 1990-91 Howmedica began manufacturing the Duracon knee, and it no longer manufactures the type of knee device involved in this case. Through the 1980's Howmedica received feedback from surgeons, and it was aware of a small number of cases where the polyethylene in this type of device was

wearing. The Duracon knee prosthesis uses polyethylene no less than nine millimeters thick because the company learned that thin polyethylene had higher stresses than thicker polyethylene. Van Syckle explained that, although an additional two millimeters of resected bone is required to implant this device, the quality of surgical instruments and techniques has improved since the earlier prosthesis was marketed, and tibial fixation is less of a problem. Van Syckle also testified that heat polishing is no longer used because new machinery is now available and because the company learned that it can use a more neutral geometry in its design. Van Syckle agreed that the manufacturing technique, namely, heat polishing, may contribute to accelerated wear of the polyethylene. He testified, however, that the thickness of the plastic used in the prosthesis at bar did not make the product unreasonably dangerous. He testified that Howmedica performed tests similar to Bloebaum's, and it was unable to duplicate the type of experience or result that Bloebaum achieved.

Howmedica's expert witness, 37-year-old orthopedic surgeon and mechanical engineer Dr. John Lyons, testified that most of his work as a doctor is related to the biomechanics of joints and replacements. He has performed over 1000 total knee replacements. Lyons testified that his examination of the plaintiff's postoperative x-rays demonstrates that the plastic component in plaintiff's prosthesis failed due to over-stress. He explained that the pattern of failure shows asymmetrical wear. Lyons testified that prior to surgery plaintiff had a 6- to 10-degree varus deformity of the tibia, referring to the bowing of the tibia. Lyons testified that the articular design of the product was not responsible for the part wearing out. Rather, the failure of the device was due to surgical misalignment of the prosthesis and the patient's postoperative activities, which created undue stress on the joint. Lyons agreed that every one of the radiologist's reports indicates that the device was in excellent alignment; however, Lyons testified that Dr. Simmons' failure to comply with appropriate medical standards when he implanted the device led to its premature failure.

Lyons testified that adverse complications which may result from a revision surgery include deep infection resulting in death, amputation of the limb, continued IV antibiotics, stiffness of the knee, prolonged immobilization, drainage, wound problems, part problems, and the

loosening of parts. Lyons testified that once you have had revision surgery you are at a greater risk of infection for subsequent revisions. Revision surgery may also lead to nerve injury resulting in pain, weakness, or numbness. In addition, hemorrhaging or hematoma may result. Finally, there is the risk of thrombophlebitis or inflammation of the veins, which can lead to clot release and secondary pulmonary embolus, which can result in death.

Lyons testified that Haudrich had his knee prosthesis implanted at age 45, and according to life expectancy tables he can expect to live another 25 years. Lyons agreed that it is possible that Haudrich would undergo three to five additional revisions. Lyons testified that revision surgery can normally cost $8,500. Other costs one may expect to incur include hospital charges for a stay of 5 to 10 days, the cost of the prosthetic device, and physical therapy costs, among others. It would not be unreasonable to anticipate each revision surgery costing $30,000.

Defendants first argue that the trial court erred in permitting plaintiff's sole expert witness, Dr. Roy Bloebaum, to testify because Bloebaum is not a medical doctor and is not licensed to remove prosthetic knee devices. A medical doctor is not required here because the issue is the condition of the product, not a medical doctor's performance. See Buford v. Chicago Housing Authority (1985), 131 Ill.App.3d 235, 86 Ill.Dec. 926, 476 N.E.2d 427 (expert on metal fatigue could testify on that issue even though not an expert on elevator design); see also Witherell v. Weimer (1987), 118 Ill.2d 321, 113 Ill.Dec. 259, 515 N.E.2d 68; Greenberg v. Michael Reese Hospital (1980), 83 Ill.2d 282, 47 Ill.Dec. 385, 415 N.E.2d 390.

Defendants next argue that there is a distinction between wear and a defect which causes the product to be unreasonably dangerous. (See Mullen v. General Motors Corp. (1975), 32 Ill.App.3d 122, 336 N.E.2d 338.) Defendants argue that in this case external forces totally unrelated to the design of the product, primarily the alignment of the prosthesis, determined how long the prosthesis would last. In particular, defendants' expert, Dr. Lyons, testified that plaintiff's device failed within three years because of excessive wear brought about by the angle of the initial implant and plaintiff's postoperative activities. However, there was also testimony that Dr. Simmons, and

every radiologist who x-rayed the knee, found it to be in proper alignment. We conclude that there was sufficient evidence to prove that plaintiff's prosthetic knee device was defective and that the defective condition injured the plaintiff. It is the province of the trier of fact to weigh the credibility of witnesses, to resolve inconsistencies, and to render a decision. (Washington v. Williams (1991), 215 Ill.App.3d 607, 610, 159 Ill.Dec. 83, 85, 575 N.E.2d 581, 583.) Upon review of the record we conclude that the trial court did not err in finding that there was sufficient evidence that the plaintiff was injured by an unreasonably dangerous condition of the Howmedica knee device.

Defendants next argue that the trial court erred by admitting evidence of approximately 100 Howmedica product-experience reports, documenting complaints Howmedica received regarding the product at issue. Between 1981, when the knee prostheses of this design were first sold, and June 1992, the beginning of trial, Howmedica sold 73,158 units of the seven-millimeter polyethylene insert prosthesis.

Charles Lawyer, director of quality assurance for Howmedica, testified that Howmedica's quality assurance department is responsible for receiving and reviewing reports of complaints concerning its products. When the quality assurance department receives a complaint, it prepares a product-experience report, documenting receipt of the complaint and stating the company's evaluation of the complaint. Lawyer testified that during the 11 years after the product was first sold, Howmedica received and documented approximately 100 reports of complaints on the 73,158 units sold.

Lawyer's testimony demonstrated that the reports admitted at trial were redacted versions of the reports prepared by Howmedica. Lawyer testified that the names of the complainant, the doctor, and the hospital were removed prior to production. Lawyer further testified that, once a complaint is filed, if the prosthetic device is not returned, Howmedica cannot evaluate it. He testified that in some of the product experience reports the company ruled out defective product design without the benefit of examining the device.

Defendants argue that the trial court erred in admitting the product-experience reports as evidence of prior similar occurrences. Defendants argue that plaintiff failed to lay any foundation for

admission of the reports as there was no evidence that the circumstances surrounding the occurrences in the reports was substantially similar to the occurrence in this case. Defendants further contend that the reports were irrelevant because they do not tend to prove the material fact in question, whether the product at issue is defective. Plaintiff argues that the reports contain complaints of premature plastic wear on the seven-millimeter prosthetic device, which forms a basis of substantial similarity to this case. Plaintiff contends that any lack of proof of similarity was caused by the defendants' production of the reports in redacted form. Plaintiff states that because the reports fail to reveal all the particulars of the incidents complained of, plaintiff was limited in demonstrating similarity other than that the reported problems involved the same type of prosthetic device and were related to polyethylene wear.

Evidence of prior similar occurrences is admissible to establish the unreasonably dangerous qualities of defectively designed products where the trial judge determines that the prior occurrences were substantially similar to the case at bar. (Rucker v. Norfolk & Western Ry. Co. (1979), 77 Ill.2d 434, 441, 33 Ill.Dec. 145, 148, 396 N.E.2d 534, 537; Bass v. Cincinnati, Inc. (1989), 180 Ill.App.3d 1076, 129 Ill.Dec. 781, 536 N.E.2d 831.) Plaintiff introduced the reports to demonstrate that the prosthesis design at issue is susceptible to unexpected polyethylene wear. It need not be shown that the wear occurred in an identical manner. Substantial similarity is sufficient. (Rucker, 77 Ill.2d at 441, 33 Ill.Dec. at 149, 396 N.E.2d at 538; Dillard v. Walsh Press & Die Co. (1991), 224 Ill.App.3d 269, 166 Ill.Dec. 567, 586 N.E.2d 525.) Under the circumstances, the trial judge did not abuse his discretion in admitting the testimony.

The final issue defendants raise is whether sufficient evidence was presented to support the award of damages assessed by the court and whether the award was so excessive as to be contrary to the manifest weight of the evidence. The trial court, in its December 2, 1992, order, assessed damages against defendants as follows:

> "for the reasonable expense of medical care, treatment and service already received and the present cash value of medical care, treatment and services reasonably certain to be received in the

future, for the value of salaries lost and the present cash value of salaries reasonably certain to be lost in the future, for the pain and suffering experienced and reasonably certain to be suffered in the future, and for the disability and disfigurement resulting from plaintiff's injuries, in the sum of $1,686,988.70."

Defendants argue that the court's damages assessment bears no rational basis to the evidence, and that the damages awarded are outrageously excessive, unreasonable, and unwarranted by the evidence.

Plaintiff has the burden to establish that he sustained damages and the burden to set forth a reasonable basis for the computation of those damages. Damages may not be awarded on the basis of conjecture or speculation. However, once damages have been determined by the trier of fact, a reviewing court will not disturb those findings unless the findings are against the manifest weight of the evidence. (Schoeneweis v. Herrin (1982), 110 Ill.App.3d 800, 66 Ill.Dec. 513, 443 N.E.2d 36.) Whether a damage award shocks the judicial conscience or is fair and reasonable must be determined from consideration of the permanency and extent of the injury, possible future deterioration, medical expenses, and restrictions on daily activity due to the injury. Rodda v. White (1991), 222 Ill.App.3d 989, 1000, 165 Ill.Dec. 445, 452, 584 N.E.2d 879, 886.

Regarding medical expenses, defendants argue that the approximate $21,000 attributable to the revision surgery is not recoverable as it is undisputed that plaintiff would have had to undergo revision surgery at some point. Although the evidence demonstrated that plaintiff would have had to undergo revision surgery in the future even had the prosthesis lasted longer, the evidence showed that a user of the device could have reasonably anticipated that it would last anywhere from 8 to approximately 10 years. The testimony revealed that once a revision surgery is performed the necessity for subsequent revisions occurs at shorter intervals. Thus, the evidence supports a conclusion that because the device failed prematurely, plaintiff had to undergo an additional revision surgery that he would not otherwise have had to undergo. Furthermore, because evidence demonstrated that subsequent revisions occur at shorter intervals, it is logical to suggest

that plaintiff will incur future medical expenses for revision surgeries he would not otherwise have had to face.

As to lost income, plaintiff testified that he earned approximately $25,000 annually working at Hecker Feed Service and suggested that his lost wages were approximately $400,000. Defendants argue that plaintiff should not be entitled to any lost wages because his initial knee surgery was only designed to allow him to continue at retirement-level activities and was not designed to allow him to return to anything other than sedentary or light-duty work. Furthermore, defendants argue that plaintiff reasonably expected to continue working seven additional years, because plaintiff's doctor, Dr. Simmons, testified that plaintiff would not be able to return to work following revision surgery, which he estimated would occur within 10 years, give or take two years.

Dr. Simmons testified that plaintiff was ordered to restrict his activities following the initial implantation. Notwithstanding Dr. Lyon's testimony that the device failed due to misalignment and over-stress, evidence showed that the device could reasonably have been expected to last approximately 10 years. Thus, the court could have concluded that plaintiff lost approximately seven years of employment income due to the failure of the prosthesis.

Defendants also contend that the record is devoid of any evidence that either pain and suffering or disability and disfigurement should be a component of plaintiff's damage award. Defendants contend that Haudrich's belaboring of the risks associated with revision surgery is misleading because such risks are present in any knee surgery, and Haudrich was due to undergo revision surgery at some point in time. Defendants maintain that plaintiff is much better off now than if he had never had total knee replacement surgery. Moreover, defendants argue that Haudrich's inabilities to play golf, go dancing, and perform other activities were limitations that were present after his initial injury and were not a result of the revision surgery.

Dr. Lyons testified that with each revision surgery there is a greater risk of complications, and the risks increase with each succeeding surgery. Although the evidence demonstrates that Haudrich may have to undergo multiple revision surgeries, this surgery may have been one additional that he would not otherwise have had to endure

absent the premature failure of the prosthesis. Finally, while admittedly Haudrich's activities were restricted following the initial knee implantation, there was evidence that Haudrich's activity level was more severely curtailed following the revision surgery.

The trial court may have concluded that as a result of the premature failure of the device Haudrich suffered lost wages from employment, will have to undergo repeated revision surgeries risking complications, will incur extensive future medical costs, and has suffered and will suffer mental and physical pain, disability, and disfigurement. Therefore, we find that the trial court's award of damages was supported by competent evidence.

Finally, defendants argue that Haudrich offered absolutely no proof at trial that Michael Lukens was negligent for selling the artificial knee device. Defendants pray that this court reverse the judgment against Lukens. Defendants failed to raise this argument in their initial brief before this court. Supreme Court Rule 341(e)(7) provides that points not raised in an appellant's initial brief are waived and shall not be raised in the reply brief. (134 Ill.2d R. 341(e)(7); see also In re Liquidations of Reserve Insurance Co. (1988), 122 Ill.2d 555, 568, 120 Ill.Dec. 508, 514, 524 N.E.2d 538, 544.) Accordingly, we find that defendants have waived this issue.

[The preceding material is nonpublishable under Supreme Court Rule 23.]

******END OF UNPUBLISHED TEXT******

In conclusion, we hold that the order of the circuit court is affirmed.

Affirmed.

MAAG and GOLDENHERSH, JJ., concur.

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APPENDIX C - JUDGMENT OF THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL CIRCUIT ST. CLAIR COUNTY, ILLINOIS DATED DECEMBER 2, 1992

DONALD HAUDRICH,)
Plaintiff,)
) 89-L-357
v.)
)
HOWMEDICA, INC., a)
corporation, and)
MICHAEL LUKENS,)
Defendants.)

FILED
Dec 02 1992

ORDER

This cause having come before the court, the court, having jurisdiction of the subject matter and the parties, and having been fully advised in the premises, finds and orders as follows:

This cause having come before the court for bench trial on Counts I and II of plaintiff's First Amended Complaint, the court having heard and considered the testimony of the witnesses and assessed their credibility, and having examined the exhibits admitted into evidence, the court finds that plaintiff has proved the allegations of his complaint by a preponderance of the evidence, and further finds that judgment should be entered for plaintiff and against defendants.

IT IS THEREFORE ORDERED THAT judgment be, and it hereby is entered, for plaintiff and against defendants for the reasonable expense of medical care, treatment and service already received and the present cash value of medical care, treatment and services reasonable certain to be received in the future, for the value of salaries lost and the present cash value of salaries reasonably certain to be lost in the future, for the pain and suffering experienced and reasonably certain to be suffered in the future, and for the disability and disfigurement resulting from plaintiff's injuries, in the sum of $1,686,988.70

Robert L. Craig
Associate Judge

APPENDIX D - ORDER OF THE ILLINOIS SUPREME COURT DATED APRIL 1, 1996

ILLINOIS SUPREME COURT
Juleann Hornyak, Clerk
Supreme Court Building
Springfield, Ill 62706

April 1, 1996

No. 78319 - Marilyn Haudrich, as Ex'r., etc., appellee v. Howmedica Inc., et al., appellants. Appeal, Appellate Court, Fifth District

The Supreme Court today DENIED the petition for rehearing in the above entitled cause.

Harrison, J., took no part.

The mandate of this Court will issue to the appropriate Appellate Court and/or Circuit Court or other agency on April 11, 1996.

APPENDIX E - STATUTORY AND REGULATORY PROVISIONS

21 U.S.C. § 360(k)

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe) –

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

(As amended Aug. 16, 1972, Pub.L. 92-387 §§ 3, 4(a)-(c), 86 Stat. 560-562; May 28, 1976, Pub.L. 94-295, § 4 (a), 90 Stat. 579.)

21 U.S.C. § 360c

(f) Initial classification and reclassification of certain devices

(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless –

(A) the device –

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate

commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b) of this section, or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) classifying the device in class I or II.

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(l) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device –

(i) has the same technological characteristics as the predicate device, or

(ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(June 25, 1938, c. 675, § 513, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 540, and amended Nov. 28, 1990, Pub.L. 101-629, §§4 (a), 5(a), (b), (c)(1), (c)(3), 12(a), 18(a), 104 Stat. 4515, 4517, 4518, 4523, 4528; June 16, 1992, Pub.L. 102-300, § 6(3), 106 Stat. 240; Aug. 13, 1993, Pub.L. 103-80, § 3(a), 107 Stat. 778.)

21 U.S.C. § 360e

§ 360(e) Premarket approval

(a) General requirement

A class III device –

(1) which is subject to a regulation promulgated under subsection (b) of this section; or

(2) which is a class III device because of section 360c(f) of this title,

is required to have, unless exempt under section 360j(g) of this title, an approval under this section of an application for premarket approval.

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain –

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission or complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title, may require.

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary –

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 360c of this title,

refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

(June 25, 1938, c. 675, § 515, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 552, and amended Nov. 28, 1990, Pub.L. 101-629, §§ 4(b)(1), 9(a), 18(c), 104 Stat. 4515, 4521, 4528; Aug. 13, 1993, Pub.L. 103-80, § 3(t), 107 Stat. 778.)

21 U.S.C. § 360j(g)

(g) Exemption for devices for investigational use

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 3603, 360f, 360i or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption –

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device

(including, where appropriate, tests on animals) adequate to justify the proposed clinical testing –

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if –

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which

necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 360f of this title) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(June 25, 1938, c. 675, § 520, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 565, and amended Nov. 28. 1990, Pub. L. 101-629, §§ 3(b)(2), 4(b)(2), 5(c)(2), 6(b)(2), 11, 14(a), 18(e), (f), 104 Stat. 4514,

4516, 4518, 4519, 4522, 4524, 4529; Oct. 29, 1992, Pub.L. 102-572, Title I, §107(10), 106 Stat. 4499.)

21 U.S.C. § 360k

§ 360k State and local requirements respecting devices

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

(June 25, 1938, c.675, § 521, as added May 28, 1976, Pub.L. 94-295, § 2, 90 Stat. 574.)

21 C.F.R. § 807.81

§ 807.81 - When a premarket notification submission is required

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b) A premarket notification under this subpart is not required for a device for which a premarket approval application under

section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration.

(c) In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in §1000.3 of this chapter, shall comply with the reporting requirements of Part 1002 of this chapter.

21 C.F.R. § 860.84

§ 860.84 Classification procedures for "old devices."

(a) This subpart sets forth the procedures for the original classification of a device that either was in commercial distribution before May 28, 1976, or is substantially equivalent to a device that was in commercial distribution before that date. Such a device will be classified by regulation into either class I (general controls), class II (special controls) or class III (premarket approval), depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the device (§ 860.3(c)). This subpart does not apply to a device that is classified into class III by statute under section 513(f) of the act because the Food and Drug Administration has determined that the device is not "substantially equivalent" to any device subject to this subpart or under section 520(l)(1) through (3) of the act because the device was regarded previously as a new drug. This subpart does apply to a device that was previously regarded as an antibiotic drug and that is subject to section 520(l)(4) of the act. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

(b) The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513(b) and (c) of the act and Part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III)

appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with Part 14 of this chapter.

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of each class in § 860.3(c), the panel submits to the Commissioner a recommendation regarding the classification of the device. The recommendation will include:

(1) A summary of the reasons for the recommendation;

(2) A summary of the data upon which the recommendation is based, accompanied by references to the sources containing such data;

(3) An identification of the risks to health (if any) presented by the device;

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the act: section 510 (registration, product listing, and premarket notification) section 519 (records and reports) and section 520(f) (good manufacturing practice regulations) in accordance with § 860.95;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement;

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device, accompanied by references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed in the Dockets Management Branch's office upon receipt and are available to the public upon request.

(f) The Commissioner publishes the panel's recommendation in the FEDERAL REGISTER, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(g) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519 and 520(f) of the act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with §860.95;

(2) If classifying the device into class II or class III, at the discretion of the Commissioner, establish priorities for the

application to the device of a performance standard or a premarket approval requirement;

(3) If classifying an implant, or life-supporting or life-sustaining device, comply with § 860.93(b).

[43 FR 32993, July 28, 1978, as amended, at 57 FR 58404, Dec. 10, 1992]

21 C.F.R. § 888.3560

§ 888.3560 Knee joint patellofemorotibial polymer/metal/-polymer semi-constrained cemented prosthesis

(a) Identification. A knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis is a device intended to be implanted to replace a knee joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across-the-joint. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and a tibial component or components and a retropatellar resurfacing component made of ultra-high molecular weight polyethylene. This generic type of device is limited to those prostheses intended for use with bone cement (§ 888.3027).

(b) Classification. Class II.

53 Fed. Reg. 51,007

53 Fed. Reg. 51,007 (Dec. 12, 1988)

[Docket No. 88M-0364]

Howmedica, Inc., Premarket Approval of P.C.A.™ Total Knee System

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Howmedica, Inc., Rutherford, NJ, for premarket approval under the Medical Device Amendments of 1976, of the P.C.A.™ Total Knee System. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 30, 1968, of the approval of the application.

DATE: Petitions for administrative review by January 18, 1989.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review of the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas J. Callahan, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910. 201-427-7156.

SUPPLEMENTARY INFORMATION: On August 13, 1985, Howmedica, Inc., Rutherford, NJ 07070, submitted to CDR14 an application for premarket approval of the P.C.A.™ Total Knee System. The device is indicated for noncemented use in skeletally mature individuals undergoing primary surgery for rehabilitating knees damaged as a result of osteoarthritis and rheumatoid arthritis. Regulatory review of safety and effectiveness data for the cemented use of the P.C.A.™ Total Knee System is not required at this time, because use of the device with bone cement has been found to be substantially

equivalent to a generic type of device marketed in interstate commerce prior to May 28, 1976 (see CFR 888.3560).

On January 22, 1988, the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1988, CDRH approved the application by a letter to the applicant from the Acting Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH -- contact Thomas J. Callahan (HFZ-410), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application AND CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identity the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 18, 1989, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: December 12, 1988.

Walter E. Gundaker,

Director, Office of Compliance, Center for

Devices and Radiological Health.

FR Doc. 88-29046 Filed 12-16-88; 8:45 am)

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No. 95-2018

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In The

Supreme Court of the United States

October Term, 1995

HOWMEDICA, INC.,

Petitioner,

vs.

MARILYN HAUDRICH, as Executor and Sole Legatee of Donald Haudrich, Deceased,

Respondent.

On Petition for Writ of Certiorari to the Supreme Court of the State of Illinois

RESPONDENT'S BRIEF IN OPPOSITION

HARRIET HOMSHER HAMILTON
Counsel of Record
COOK, SHEVLIN, YSURSA,
BRAUER & BARTHOLOMEW, LTD.
Attorneys for Respondent
12 West Lincoln Street
Belleville, Illinois 62220
(618) 235-3500

9064
Lutz Appellate Services, Inc.
(800) 3 APPEAL • (800) 5 APPEAL • (800) BRIEF 21

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ADDITIONAL BACKGROUND AND FACTS

In the course of trial Howmedica's officer in charge of FDA compliance (a lawyer named Charles Lawyer), was cross-examined in respondent/plaintiff's case in chief. (Tr. pp. 269-316). Howmedica produced about 100 adverse incident reports which were addressed on this examination. *Id.* The system to track such incidents had only been in place for about two years prior to trial. *Id.* These reports were redacted to remove the patients' names and other personal data, but they concerned plastic failure, which was the alleged defect in this case. *Id.* Lawyer could not identify the report on the respondent's decedent or another client of respondent's trial counsel. *Id.* Lawyer suggested these may be the only two oversights. *Id.*

Lawyer also testified about the requirement to provide Medical Device Reports to the FDA within five days of notice to the manufacturer by a physician of a serious injury caused by the device. *Id.* Nonetheless, he had not submitted such a report to the FDA on this case. *Id.* Lawyer explained he never read the patient's physician's trial deposition in this case taken in March, 1991 (wherein such information was contained). He testified Howmedica had never concluded a device was at fault for a reported failure. *Id.* Those conclusions were made although in many instances the devices were not retrieved, medical records were not obtained and no other investigation was done to determine the reason for the failure. *Id.*

Despite the presence at trial of this employee, petitioner did not present evidence about the scheme of the Medical Device Amendments 21 U.S.C. § 360 *et seq.* (MDA) to classify devices, the process of FDA approval or the classification of the PCA Knee Device under the MDA which was exhaustively described in petitioner's brief , pages three to six.

Respondent's expert, Roy Bloebaum, Phd., was highly qualified in the field of failure analysis of prosthetic devices. (Tr. pp. 73-118, 185-191). He was a full professor at the University of Utah School of Medicine, Division of Orthopedic Surgery and was also employed at the Bone and Joint Research Lab of the VA Medical Center, Salt Lake City. *Id.* Independent of his participation in this case, he had performed failure analysis of the PCA type knee in the course of his work at the VA Center. *Id.* Among other criticisms of the device at issue he testified to a reasonable degree of scientific certainty that the product was defective and unreasonably dangerous because the polyethylene plastic portion was too thin and such defect contributed to the premature failure of the device. *Id.*

Petitioner asserted a preemption defense for *the first time* before the Fifth District Appellate Court of Illinois. Attached to their brief then was the C.F.R. and Federal Register excerpts which now appear in petitioner's brief (App. E, pp. 63a-66a). Petitioner sought judicial notice of those documents and if acceptable, they would be the only material of record demonstrating the classification of this device.

REASONS FOR DENYING THE WRIT

I.

CONGRESS DID NOT INTEND TO PREEMPT THE CAUSES OF ACTION PLEADED IN THIS CASE.

This case is resolved by the result in *Medtronics v. Lohr,* #95-754 and 95-886, WL 345805. In their brief petitioner has suggested facts and inferences about the status of the device that inaccurately color the merits of the defense asserted herein. Most assuredly to gain a better stand they incorrectly posture the preemption claim as one concerning a Class III device with

premarket approval, and/or an investigational device exemption (IDE). Accepting for the sake of argument that the court can take judicial notice of the evidence in the C.F.R. and Federal Register that premarket approval was granted for the device, it was not conferred until 1988, about three years after the device was implanted. Moreover, while petitioner's refer to an IDE for this device they do not mention there was no evidence the surgeon who implanted this device was part of any FDA approved test of the product. Most importantly, there is *nothing* in the trial record of this case documenting acceptance of the product into the IDE program. As such there is no record citation to the claim in petitioner's brief about an IDE for this device (Pet. Brief, p. 6) and respondent has never admitted those facts. What petitioner seeks is to have this court apply premarket approval retroactively, or find an investigational device exemption existed where there is no evidence it was authorized.

Perhaps the fatal flaw in Howmedica's preemption argument is that while they argue Congress clearly intended to preempt the claims asserted and provide this extraordinary, pervasive defense their own inaction defies such characterization. If the intent was so patent, why didn't this sophisticated manufacturer, (who had an attorney employed as the FDCA regulatory compliance manager), fail to raise the defense in the trial court over 15 years after the MDA's enactment?

Any preemption analysis should be made on the basis of the status of the device in September, 1985 when it was implanted or earlier when it was sold. By petitioner's own facts, in 1985 the prosthesis was a Class II device with marketing approval through the 510k process. (Pet. Brief, p. 6). As such, *Medtronics v. Lohr,* WL 345805, controls the result herein and there is no preemption of any of the claims.

II.

ANY PREEMPTION DEFENSE UNDER MDA (IF IT EXISTS) IS WAIVABLE, AND DEFENDANT DID WAIVE IT BY FAILING TO RAISE IT AS AN AFFIRMATIVE DEFENSE IN THE TRIAL COURT.

The Illinois Supreme Court correctly analyzed the case under *International Longshoreman's Ass'n v. Davis,* 476 U.S. 380 (1986), and determined that if there was a preemption defense, it was waived by defendant herein. Petitioner erroneously attempts to analogize the FDA to the NLRB. *Davis* instructs that for a defense to constitute subject matter jurisdiction it must be a matter of a forum question rather than a choice of law. *Id.* In this case the Illinois Supreme Court correctly determined that unlike the NLRB, the FDA was not an alternative forum for dispute resolution and the question was whose law controlled. (Pet. Brief, App. A). The Illinois Court's opinion is completely consistent with the opinion in *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8 (1st Cir. 1995) (holding MDA preemption defense could be waived), and other federal courts analyzing the nature of other statutes providing a defense of federal preemption. (Ill. Sup. Ct. Op. and cases cited therein, at Pet. Brief, App. A., p. 11a).

While the waiver issue was not specifically before the court in *Medtronics v. Lohr,* WL 345805, by inference it is resolved by the result therein. For petitioner to be correct in their assertion that the Illinois Court lacked subject matter jurisdiction there could be no private enforcement of FDCA requirements. A consensus of the Court in *Medtronics* found if a product did not comply with an FDCA requirement no conflict would arise from a state civil action brought to enforce such requirement. *Id.* Accordingly, the state court in Illinois had jurisdiction over the

matter of whether a conflict existed, and under Illinois rules the defense should have been presented for consideration in the trial court. (Pet. Brief, App. A).

In that the matter was not raised in the trial court proceedings very little information is in the record regarding the FDA's actions on this device. What *is* known is Howmedica only had a system in place as of about 1989 to monitor complaints about the device. A further questionable practice is suggested by the fact that despite sworn testimony of a treating physician about a serious injury caused by the device, no Medical Device Report was made to the FDA of that opinion. Finally a question of compliance is raised concerning why this device was implanted without bone cement three years before it was approved for use in that manner.

As well described in the Illinois Supreme Court's decision in this case, (Pet. Brief, App. A), waiver is an equitable doctrine. It abides by a simple principle of fair play: if one party fails to raise an issue they cannot later cry foul, because by their own inaction or trial tactics they denied the opposing party the opportunity to substantively respond. *Id. Medtronic v. Lohr* confirms respondent was prejudiced by petitioner's failure to timely raise the defense because serious questions of compliance with FDA regulations are apparent. Respondent was denied any opportunity to further discover or plead any matters concerning compliance with the regulations.

CONCLUSION

For the reasons stated herein and those contained in the lower courts' opinions, respondent asks this court to deny the petition for writ of certiorari.

Respectfully submitted,

HARRIET HOMSHER HAMILTON
Counsel of Record
COOK, SHEVLIN, YSURSA,
BRAUER & BARTHOLOMEW, LTD.
Attorneys for Respondent
12 West Lincoln Street
Belleville, Illinois 62220
(618) 235-3500

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SUPPLEMENTAL BRIEF FOR PETITIONER

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE & FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record

Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350
Counsel for Petitioner

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Petitioner Howmedica Inc. ("Howmedica") hereby submits this supplemental brief in light of this Court's decision in *Medtronic, Inc. v. Lohr*, 64 U.S.L.W. 4625 (U.S. June 26, 1996).

This Petition now presents directly a question that was subsumed in the question presented in the Petition but not resolved by the Court's narrow decision in *Medtronic*: whether the Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360 *et seq.* (1994), pre-empt a state-law action directed at a medical device that actually passed the Food & Drug Administration's ("FDA") scrutiny, particularly where the action challenges design or manufacturing features of the device that obtained specific FDA approval.

ARGUMENT

In *Medtronic*, this Court addressed the question whether state-law tort claims involving the design, manufacture, and labeling of a medical device that had not completed the "premarket approval" or "PMA" process are pre-empted by 21 U.S.C. § 360k(a) (1994) (App. 58a). The pacemaker at issue was a "Class III" device that was permitted to be marketed pursuant to the "§ 501(k) process," following a determination by the FDA that the device was "substantially equivalent" to similar devices. The Court held that design defect claims were not pre-empted because the FDA never approved the design of this particular device, see 64 U.S.L.W. at 4631-32 (opinion of STEVENS, J.); *id.* at 4637 (O'CONNOR, J., concurring in part and dissenting in part), and that claims based on negligent manufacturing and labeling also were not pre-empted because the device was subject only to FDA regulations on manufacturing and labeling of general applicability, and not specific to this particular device. *Id.* at 4633-34 (Opinion of STEVENS, J.).

This case, however, involves a device that has successfully completed the FDA's rigorous PMA "gauntlet," after first being authorized for use as an experimental device in a clinical investigation pursuant to the FDA's Investigational Device Exemption ("IDE") process. See 21 U.S.C. § 360j(g) (1994) (App. 54a-58a); 21 C.F.R. Pt. 812 (1995). Thus, this case presents an issue of national importance that has not been resolved by *Medtronic* regarding the nature and scope of pre-emption for Class III devices that have been fully reviewed and approved by the FDA, and the subject matter jurisdiction of state courts over such claims generally.

A. The IDE-Approved and PMA-Approved Device At Issue And Plaintiff's Claims of Design Defect

The device at issue in this case is known as the P.C.A.® Total Knee System. The regulatory history of this particular device is set forth in detail in *Dawson v. Howmedica, Inc.*, 886 F. Supp. 1402 (E. D. Tenn. 1995); a summary follows.

When first introduced in 1981, the FDA classified the device as a Class II device labeled for use only with bone cement, and cleared it by the § 501(k) process. Later in 1981, Howmedica sought FDA authorization to conduct a clinical study and investigation of the use of the device *without* bone cement. The FDA granted approval of the IDE and authorized a clinical investigation early in 1982. The device that was implanted in plaintiff was utilized during the period in which the IDE clinical investigation was underway.

When the clinical investigation was completed, Howmedica submitted a PMA application for the device to be labeled for use without bone cement in 1984. 53 Fed. Reg. 51,007 (Dec. 12, 1988) (App. 64a-66a). After considering the application, including data on the safety and effectiveness of the device, the FDA granted premarket approval in 1988. *Id.* As a result, the P.C.A.® Total Knee System is now classified as a Class III device, having completed two full rounds of intense FDA scrutiny--first pursuant to the IDE process, and subsequently pursuant to the PMA process.

Notwithstanding the FDA's critical role in authorizing the development, marketing and use of this device, following a satisfactory demonstration of its safety and effectiveness, plaintiff's decedent was permitted to bring an action in Illinois state court complaining that the device was defective and unreasonably dangerous in its design. At trial, the expert testimony focused on two design criteria. First, plaintiff's experts contended that a certain polyethylene plastic tibial insert component was "too thin," *i.e.*, being 7 millimeters in thickness rather than 9 millimeters (one of a range of other thicknesses also approved by the FDA) (App. 4a-7a, 40a-41a, 44a). They also criticized the heat-polishing technique utilized to fabricate this component (App. 6a-7a, 39a-41a). Based on this testimony, the trial

court held that the device was defective and unreasonably dangerous and awarded $1,686,989.70 in damages.

B. Federal Pre-emption for IDE-Approved and PMA-Approved Devices

Congress unquestionably was motivated by a concern for protecting public health and safety when enacting the MDA. At the same time, however, Congress recognized the need to encourage innovation in medical technology and to protect against disparate state-law requirements that might stifle such innovation, particularly with regard to new and experimental devices like the one at issue here. See, e.g., *Medtronic*, 64 U.S.L.W. 4631, n.12 (Opinion of STEVENS, J.) (noting the "[s]pecial statutory exemptions" for investigative, experimental devices); H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976).

The MDA, pursuant to the IDE process, exempts investigational devices from a number of requirements for devices, including the requirements relating to a demonstration of the safety and effectiveness of the device pursuant to the PMA process for Class III devices. See 21 C.F.R. § 812.1(a) (1995). These exemptions are explicitly intended to encourage innovation and experimentation in cases where extraordinary medical remedies are warranted. See 21 U.S.C. § 360j(g) (1994) (App. 54a-58a). To receive approval under the IDE process, the manufacturer must submit a detailed application describing the device and setting forth a plan for studying its use in human subjects during the period of experimentation. See 21 C.F.R.§ 813.20 (1995). The recipients of a device who are part of the IDE study are informed of the device's investigational status and the risks involved. See 21 U.S.C. § 360j(g)(3)(D) (1994) (App. 56a-57a); 21 C.F.R. § 813.66(a)(6) (1995). During the study period, an institutional review committee monitors the clinical investigations instituted pursuant to the IDE process. See 21 C.F.R. § 813.65 (1995). The FDA ultimately will not approve an IDE absent a determination that the device has sufficient promise of being proved safe and effective, through the clinical investigation, to justify the risk of its experimental use in human beings. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th

Cir.), *cert. denied*, 506 U.S. 917, 113 S. Ct. 327, 121 L. Ed. 2d 246 (1992).

Howmedica fully complied with the requirements of the IDE process when obtaining FDA approval of its application. See *Dawson*, 886 F. Supp. at 1405 (noting that the purpose of Howmedica's IDE investigation "was to determine the safety and effectiveness of the [device] in patients undergoing non-cemented total knee joint replacement"). Included within the information required to be submitted prior to approval of the IDE was detailed information on the manufacturing, quality control, and packing and labeling procedures concerning this specific device, as well as information concerning the protocol for the clinical study and the proposed investigators. *Id.* at 1405-07. Following FDA approval, the IDE remained in effect until Howmedica subsequently obtained FDA approval as a Class III device pursuant to the PMA process.

The PMA process similarly requires manufacturers to submit to the FDA samples of the device and its proposed labeling together with extensive information. See 21 U.S.C. § 360e(c) (1994) (App. 53a-54a); 21 C.F.R. § 814.20 (1995). First and foremost, the manufacturer must submit "full reports of all information" concerning investigations to determine the safety and effectiveness of the device, such as the results of the IDE investigation in this case. 21 U.S.C. § 360e(c)(1)(A) (1994) (App. 53a). In addition, the manufacturer must submit information concerning (i) the device's basic qualities, including its design, components, properties, and principles of operation, (ii) its production, including its manufacturing methods, processing, packaging, and installation, (iii) its performance standards, if any, and (iv) any other information requested by the FDA. See *id.* § 360e(c)(1)(B)-(D), (G) (1994) (App. 53a).

A PMA application is first referred to a panel of experts, 21 U.S.C. § 360e(c)(2) (1994) (App. 53a-54a), after which the FDA can either approve the device or request additional information or testing. *Id.* § 360e(d) (1994). Final approval can be granted only if the FDA finds there is a "reasonable assurance" that the device is "safe and effective," after "weighing any probable benefit to health from the device against any probable risk of illness or injury from such use." *Id.*

§ 360c(a)(2) (1994); 21 C.F.R. § 860.7 (1995). As this Court highlighted, "[d]espite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance' . . . is a rigorous one." *Medtronic*, 64 U.S.L.W. at 4627 (Opinion of STEVENS, J.). Thereafter, the manufacturer must maintain detailed records and report to the FDA regarding the device. 21 U.S.C. § 360i (1994).

In short, both investigational devices approved through the IDE process, and Class III devices approved through the PMA process, are regulated by the FDA in virtually every respect--including their design, manufacture, labeling, distribution, and subsequent performance in actual use. For these reasons, both processes can only be viewed as constituting a "specific requirement" within the meaning of the FDA's own pre-emption regulations, 21 C.F.R. § 808.1(d) (1995), thereby implicating the full pre-emptive sweep of 21 U.S.C. § 360k(a) (1994). E.g., *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 541 (3d Cir.), *cert. denied*, ___ U.S. ___, 115 S. Ct. 429, 130 L. Ed. 2d 342 (1994) (IDE process); *King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 510 U.S. 824, 114 S. Ct. 84, 126 L. Ed. 2d 52 (1993) (PMA process); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422, n.3 (5th Cir.), *cert. denied*, 510 U.S. 824, 114 S. Ct. 86, 126 L. Ed. 2d 54 (1993) (PMA process); *Slater*, 961 F.2d at 1332 (IDE process).

Indeed, this case bears a striking resemblance to the hypothetical used by Justice Breyer to demonstrate that state tort laws can and do establish product requirements and therefore may be pre-empted by federal regulation. *Medtronic*, 64 U.S.L.W. at 4635 (BREYER, J., concurring in part and concurring in the judgment). Instead of involving the appropriate length for wires with hearing aids, this case involves the appropriate thickness of a particular component of a replacement knee joint. Here, the FDA had approved investigational use, and later general marketing, of this product with a 7 millimeter thickness (as well as with other thicknesses), but an Illinois trial court rejected that thickness, concluding that it left the product in an unreasonably dangerous and defective condition, based on the testimony of plaintiff's experts, who felt that a thickness of 9 millimeters was more appropriate for the component in question.

As Justice Breyer points out, an Illinois state agency could not issue a regulation requiring a minimum 9 millimeter thickness for this component. Yet "[t]he effects of the state agency regulation and the state tort suit are identical." *Medtronic*, 64 U.S.L.W. at 4635 (BREYER, J., concurring in part and concurring in the judgment). Upholding the damages award in this case--which is based on a state-law claim that the device is unreasonably dangerous--will have "the effect of establishing a substantive requirement for a specific device," 21 C.F.R. § 808.1(d) (1995), that plainly relates to its "safety and effectiveness." 21 U.S.C. § 360k(a)(2) (1994). Such an award could only be based on a finding that the device was *un*safe, *in*effective, or *un*fit for use, in which case the manufacturer would be forced either to alter its design and manufacturing processes or to be subject to liability despite the FDA's considered determinations--pursuant to its exclusive regulatory authority--that the device first showed sufficient promise of being proved safe and effective to justify the risk of its experimental use in human beings, and after clinical study, that the device has been demonstrated to be "safe and effective" and hence fit for general use. This would, as a practical matter, reflect "second guessing" of the FDA's expertise and experience with medical devices by lay jurors or a court. Congress surely did not intend to condone such a result when enacting § 360k(a) as part of its comprehensive regulatory scheme for the integrated IDE and PMA processes.

Manufacturers of innovative devices already confront formidable hurdles when attempting to successfully reach the market and recoup their investment in critical life-saving or life-enhancing technology. For those who already have to first comply with the clinical investigation requirements of the IDE process following invention of the device, and thereafter satisfy the grueling PMA process and maintain a continuous reporting relationship with the FDA, adding a second level of random-order scrutiny of their devices--with all the vagaries of conflicting state laws and procedural rules as well as jury verdicts--can only add to the uncertainties they face, with the very real prospect of discouraging innovation.

C. The Important Federal Question Presented

The Illinois Supreme Court held that the FDA's exclusive domain over medical devices did not reflect a choice by Congress to vest that agency with sole authority to address issues involving their safety and effectiveness (App. 10a-11a). But as *Medtronic* makes clear, when the FDA formally approves the investigative use of a device to determine its ultimate safety and effectiveness by the IDE process, or the general marketing of a device pursuant to the PMA process, thereby establishing "specific requirements" for that device, § 360k(a) divests states of any authority to impose "additional" or "differing" requirements with regard to the design, manufacture, labeling, or use of the device, whether by statute, regulation, or damages awards based on findings that the device is unreasonably dangerous or unfit for use.

This Petition asks the Court to determine whether, in light of its holding in *Medtronic*, MDA pre-emption for IDE-approved and PMA-approved devices is jurisdictional in nature and thus deprives state courts of the ability to review the safety and efficacy of devices that have already been determined suitable for investigative use or completed the most rigorous FDA review. Only by recognizing the jurisdictional nature of the pre-emption accorded IDE-approved and PMA-approved devices can the FDA's exclusive authority be properly effectuated consistent with the intentions of Congress.

CONCLUSION

For all the foregoing reasons, this Court should grant certiorari in this case and reverse the holding of the Illinois Supreme Court. At a minimum, this Court should vacate and remand this case for consideration in light of *Medtronic*.

Respectfully submitted,

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE &
FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record
Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350

Counsel for Petitioner

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REPLY BRIEF FOR PETITIONER

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE & FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record

Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350
Counsel for Petitioner

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Petitioner Howmedica Inc. ("Howmedica") hereby submits this reply brief in response to Respondent's Brief in Opposition. As pointed out in Petitioner's previously filed Supplemental Brief in light of this Court's decision in *Medtronic, Inc. v. Lohr*, 64 U.S.L.W. 4625 (U.S. June 26, 1996), the Petition presents a question that was not resolved by the Court's decision in *Medtronic*: whether the Medical Device Amendments of 1976 (the "MDA"), 21 U.S.C. § 360 *et seq.* (1994), pre-empt a state-law action directed at a medical device that has actually passed the Food & Drug Administration's ("FDA") scrutiny.

ARGUMENT

Respondent attempts to divert the Court's attention from the question presented by suggesting that there are factual issues rendering this case unsuitable for review. Although Petitioner disagrees with Respondent's assertions as to the record below, none of Respondent's contentions goes to the certworthiness of the Petition save one: the claim that the device at issue, known as the P.C.A.® Total Knee System, was a Class II device marketed pursuant to the § 510(k) process, Respondent's Brief in Opposition at 3, rather than a device authorized for use as an experimental device in a clinical investigation pursuant to the FDA's Investigational Device Exemption ("IDE") process. See 21 U.S.C. § 360j(g) (1994) (App. 54a-58a); 21 C.F.R. Pt. 812 (1995).

The regulatory history of this particular device is set forth in detail in *Dawson v. Howmedica, Inc.*, 886 F. Supp. 1402, 1406-07 (E. D. Tenn. 1995). The FDA granted Petitioner's IDE application in 1982, and the device that was implanted in plaintiff in 1985 was utilized during the period in which the IDE clinical investigation was underway. *Id.* at 1406. At a later date, the FDA granted premarket approval. 53 Fed. Reg. 51,007 (Dec. 12, 1988) (App. 64a-66a). As a result, Respondent's claim that the device is unreasonably dangerous by reason of design defects directly attacks the FDA's reasoned judgment to permit the device to be investigated under the IDE process, and thereafter marketed generally after having undergone the exhaustive PMA process.

This case therefore presents a significant issue that has not been resolved by *Medtronic* regarding the nature and scope of pre-emption for Class III devices that have been fully reviewed and approved by the FDA under the IDE/PMA process, and the subject matter jurisdiction of state courts over such claims generally.

CONCLUSION

For all the foregoing reasons, this Court should grant certiorari in this case and reverse the holding of the Illinois Supreme Court. At a minimum, this Court should vacate and remand this case for consideration in light of *Medtronic*.

Respectfully submitted,

Steven C. Kany
Louis B. Bernstein
PFIZER INC.
235 E. 42nd Street
New York, NY 10017
(212) 573-2323

James V. O'Brien
Thomas L. Caradonna
LEWIS, RICE &
FINGERSH, L.C.
500 N. Broadway, Ste. 2000
St. Louis, MO 63102
(314) 444-7600

Barry Levenstam
Counsel of Record
Stephanie A. Scharf
Matthew M. Neumeier
JENNER & BLOCK
One IBM Plaza
Chicago, IL 60611
(312) 222-9350

Counsel for Petitioner

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